TECHNICAL REPORT

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Guidelines for interpretation of ISO 9000 series for application within the iron ore industry

Lignes directrices pour l'interprétation de la série ISO 9000 dans son application à l'industrie des minerais de fer

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardisation.

The main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

- type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

- type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

- type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 13352, which is a Technical Report of type 3, was prepared by Technical Committee ISO/TC 102, *Iron ores.*

Introduction

There is a keen interest both in iron ore producers and their customers for the adoption of quality management and assurance systems on the basis of the ISO 9000 series. In considering the relative advantage of third party audit based on the ISO 9000 series against internal quality audit however there is some concern regarding the lack of consistency amongst quality auditors in third party and the emphasis of formal certification on "the systems" rather than method and performance in third party audit. In consequence it was strongly felt that these difficulties can best be addressed by preparing guidelines for application of the ISO 9000 series that are tailored specifically to the iron ore industry. This Technical Report has been thus prepared.

The principle of the ISO 9000 series is to make a product or process **"RIGHT THE FIRST TIME".** The standard's whole purpose is to help organizations achieve this objective and to reduce nonconformities in the quality of products to the minimum. The result is increased customer satisfaction, but most organizations also reduce operating costs and create a better working environment.

To achieve this objective ISO has provided a quality system checklist in the form of the ISO 9000 standards. A quality system therefore should be as comprehensive as needed to meet the following quality objectives:

- to achieve and sustain product or service quality necessary to continually meet the customer's stated or implied needs;

- to provide confidence to management that the intended quality is being achieved and sustained and

- to provide confidence to the customer that the intended quality is being achieved in the delivered product.

This means that the product provided to customers should have a level of quality appropriate to its purpose. ISO 9000 registration, when achieved, is of the supplier's quality system and does not in any way imply certification of the product. Registration demonstrates that the supplier has implemented a quality system for the products or services provided and that the systems are in place to produce the customer's specified product requirements.

- As you work on your documentation, a tiered approach is suggested. At the corporate level have a manual that makes statements of general intent for your quality system. The details of how the intent is implemented are dealt with at the divisional and departmental level.

- Don't try to write procedures that cover every possible eventuality. This is an impossible task. Rather write them as general guidelines and defer decisions to the judgment of a responsible person.

- Ensure that you are following your own procedures. If you are not following your procedures then question the validity of the procedure or task before you try to enforce it.

- As you develop the quality system, try to build on your existing quality procedures. They may need further development or modification but do not duplicate what exists (and has been effective) by overlaying a whole new layer of bureaucracy and paperwork.

- Keep the system as simple as possible and don't do anything that does not have business value. If an ISO 9000 requirement does not have business value you have probably misinterpreted the requirement. The whole objective of the ISO 9000 series is to make the business process more effective, not more cumbersome and rigid.

The benefit of ISO 9000 registration is in the process that you go through to achieve this. The benefit is in the detailed thought and analysis that takes place as a result of having to describe and document what you should be doing to run your business. Preparing the documentation makes each person involved in the process think out and appreciate the sequence of events step by step.

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Guidelines for interpretation of ISO 9000 series for application within the iron ore industry

1 Scope

This Technical Report gives guidelines for the interpretation of the ISO 9000 series for application within the iron ore industry, including the mining, concentrating, pelletizing and shipping processes.

This Technical Report will serve as a guide to help iron ore producers develop a quality system that can be registered to the ISO 9000 series of quality management standards. The quality system elements have been directly matched to ISO 9001 that includes all quality system elements of ISO 9001, ISO 9002 and ISO 9003. It is assumed that ISO 9001 is appropriate to the iron ore industry only when a strong design element for new product development exists.

2 References

The following standards relate to this Technical Report:

ISO 8402:1994, Quality management and quality assurance — Vocabulary.

ISO 9000:1994, Quality management and quality assurance standards — Guidelines for selection and use.

ISO 9001:1994, Quality systems — Model for quality assurance in design development, production, installation and servicing.

ISO 9002:1994, Quality systems — Model for quality assurance in production, installation and servicing.

ISO 9003:1994, Quality systems — Model for quality assurance in final inspection and test.

ISO 9004:1994, Quality management and quality system element guidelines.

ISO 10011-1:1994, Guidelines for auditing quality systems — Part 1: Auditing.

3 Terms and definitions

3.1 Throughout this Technical Report, the definitions given in ISO 8402 are applicable.

3.2 In the following clause, **"INTENT"** is the interpretation of the purpose of the respective clause, and **"GUIDELINES"** provides guidance or information for instruction for application by iron ore producers and "the standard" is that particular ISO 9000 standard that is applicable.

4 Guidelines for quality system requirements

In the following, sub--clause numbers for respective quality system requirements are the same as those in ISO 9001.

4.1 Management responsibility: In general terms, management's responsibility is to; create the quality policy, develop and staff the quality organization, provide verification resources, appoint a management representative and conduct management review of the quality system. Looking at each of these in turn:

4.1.1 Quality policy

INTENT This should be a clear demonstration of top management's commitment to the stated objectives and procedure that form the quality system.

GUIDELINES The quality policy should contain a commitment statement from top management, but it should also contain a series of objectives to support the policy. The objectives should be specific and measurable to ensure the effectiveness of the program. Management review should be able to assess progress against the policy objectives. The policy should be understood, it should be implemented and maintained at all levels within the company.

In reviewing your quality objectives address the question "What objectives would our customers like to see us achieve?"

You may wish to add quality objectives to your policy that are not specifically required by the standard but be careful of doing so. Whether or not elements are required by the standard if you include them in your quality system you may be audited to them.

4.1.2 Organization

4.1.2.1 Responsibility and authority

INTENT Definition of the responsibility and authority for quality of the various positions in the organization.

GUIDELINES You should define the authority, responsibility and interrelationship of the people who manage and perform those activities that impact on quality. An organizational chart is mandatory. Specify who within the organization has the freedom and responsibility to:

- prevent noncomformities;
- identify and record product quality problems;
- provide solutions through the system;
- verify the solution, and
- who has the authority to release nonconforming product.

4.1.2.2 Resources

INTENT To ensure that sufficient resources and personnel are designated to measure compliance with customer requirements.

GUIDELINES The standard requires the provision of adequate resources and trained personnel for the complete process. This needs to be documented. In the documentation identify verification needs including inspection, testing and monitoring. Staffing for these activities should be shown on a separate organizational chart. Process, product or system audits should be independent, that is carried out by people not involved in that part of the operation.

4.1.2.3 Management representative

INTENT One person responsible for maintaining the integrity of the quality system.

GUIDELINES One person should be responsible for the quality system and have the authority to implement it. The management representative can hold other positions and need not be responsible only for quality but on quality he or she should have the freedom to ensure the quality requirements are not subordinated to the dictates of production, maintenance or delivery. More specifically, the main function of the management representative is to ensure the system is maintained as described in the quality system manuals, and to co-ordinate regular audits of the system, analyse results and resolve nonconformity problems, and bring forward improvements for senior management approval.

4.1.3 Management review

INTENT To assess current quality system activities against customer, company, or ISO 9000 requirements and to review progress against the stated quality objectives.

GUIDELINES The review should be conducted by the senior members of the management team with support from those who report directly to them. The review should be scheduled at regular intervals to ensure continuing suitability and effectiveness of the quality system. Records should be kept of the results of the reviews and the actions taken to improve the system. The management review is done against the quality policy objectives and internal and external quality audits. Topics of discussion should be quality costs, customer complaints, results of product and system audits, effectiveness of the system, frequency of noncomformities, and results of corrective action, implementation of system changes, training levels, etc. Management review will receive extreme scrutiny during an audit as it can quickly identify the level of management commitment.

4.2 Quality system

The fundamental requirement for registration of a quality management system is documentation in the form of a **quality plan and quality manual.** This documentation communicates:

- company policy on quality;
- company organization to implement that policy, and
- how tasks will be performed to achieve the objectives in that policy.

4.2.3 Quality planning

INTENT To ensure a systematic approach to product quality planning is in place and effective.

GUIDELINES A quality plan means a description of the process upon which your business is based. Specifically a quality plan is defined as "A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product service, contract or project." A quality plan may be used to provide a vehicle for the supplier to demonstrate to the customer that the specific quality requirements of a particular contract are being appropriately planned and addressed. In this case, this should be a separate controlled document that describes each component of your process from mining to shipping.

The quality plan should show key control points. Show what control action (if any) is used and what testing is carried out at each stage. It is not mandatory that control and testing be performed for each component but some testing and control should be demonstrated. Include references to raw material specifications and quality control procedures, process control, intermediate and finished product specifications and quality control procedures, and sampling procedures.

The quality plan should be area specific and be referenced to the overview corporate quality plan.

A flowchart supported by a narrative is a good way to present the quality plan. The narrative should give the details of the process, testing and method of control. This document is used as an overview document and a focus for the development of the quality manual and related procedures. A number of your procedures cut across areas of responsibility. This is where most systems problems occur. Flow charting involves the people who cut across these areas to ensure that the interface operates efficiently.

It is recommended that your Quality Manual be kept simple (depending on the company structure) and generic and that it adopt a tiered approach to your documentation. The **"level one"** documentation is the quality manual that should reflect corporate quality policy and related quality assurance procedures. This would become the master or overview manual that addresses all elements of the standard.

The **"level two"** documentation could be a quality manual for each key segment of your operation, i.e., the mine, concentrator, pelletizing plant and shipping facilities should each have an individual manual that supports the corporate quality policy and focuses on the specific elements pertinent to that area. These subsection manuals should each contain the local organization (including quality) and the responsibility of the local management representative. These area representatives should then report to the overall management representative for the company's quality system.

Each departmental system manual would be supported by **"level three"** documentation that includes the relevant standard operating procedures, calibration procedures, etc.

The **"level one" and "level two"** manual format should be based on the standard. The "lower levels" should be based on your specific organizational structure and area of responsibility. The lower levels should also be cross-referenced to the master **"level one"** manual.

All customer specifications, both internal and external could be contained in a separate manual referenced from the corporate one, depending on the number of contracts.

Do not include proprietary processes or detailed operating procedures in your **"level one"** manual. These should go into the lower level manuals and standard operating procedures that are referenced from the **"level one"** manual. Keeping the manual free of either proprietary information or detailed procedures doesn't restrict circulation and the manual can then form a powerful sales and marketing tool .

All elements and sub-elements of the standard that are applicable to each area must be addressed and exception taken to the elements that are not. The exceptions page can be placed anywhere in the manual but 4.2 is the suggested location. It should contain a brief description of the rationale for each exception, e.g.,

"**Mine Quality System**

Exception

- Contract Review

This procedure is not applicable to the mine as the sales department deals with the external customer. This procedure is contained in the corporate manual. The mine can feed information to the sales department as required, particularly regarding trace elements."

It is convenient to divide the manual into two sections. The **front matter** up to and including 4.2 of the ISO 9000 series standard that contains the policies, definitions, organizational structures: and the **elements** that are the procedures required to implement the policies.

Front matter

The following few headings describe the sort of information to be included in the front matter:

Title, scope and field of application Defines the portion of the organization covered by the manual and the products covered by the manual. It also specifies which standard the system is designed to satisfy.

Distribution record Details manual edition, date of edition and circulation of manual.

Table of contents Describes the document layout (e.g., element revision, number of pages in element).

Introductory pages A brief description of the ownership, facilities and operations of the company.

Quality policy and objectives Description of the organization's policy on quality and supporting objectives.

Organization, responsibility and authority A specific delegation of authority for all quality matters to the person designated as the management representative. Also includes your organizational chart and quality responsibilities of those concerned.

Elements

The procedures to follow under 4.3 to 4.20 are regarded as the **"elements."** When writing the procedures for the elements it is advisable to use a standard format. This is especially true where you have the various procedures being written by different people. The following headings are suggested, **Purpose, Scope, Responsibility and Outline.**

4.3 Contract review

INTENT To ensure that the product and/or service to be exchanged is clearly defined and understood by all concerned parties.

GUIDELINES Contract review deals with your relationship with your customer. Contract is used here in the most general sense, to include phone orders, purchase orders, catalogue orders, blanket orders all commercial transactions. You need to clearly define and document who is responsible for each function to avoid confusion. Responsibility must be specified for negotiating a contract with the customer for your iron ore pellets, concentrates, etc. It should address the process of determining the operator's ability to produce both the tonnage and the quality requirements, i.e., %Fe, %SiO2 trace elements, structure, etc. There should be a procedure for resolving differences between the tender and contract, resolving ambiguities, etc. Records should be kept of each contract review.

A simple format is suggested that includes space for comments from the operations, quality and sales group.

4.4 Design control

INTENT To ensure that customer product requirements of specification and performance are satisfied.

GUIDELINES For many companies, product design (or product development) has become an important function in the iron ore industry because of change in product characteristic requirements and as well new product application.

When minor product modifications are made but the application remains the same, the new product characteristic can be implemented through the process control procedure (see 4.9).

However for major product modifications or new applications these elements of the standard (ISO 9001 only) are good practice to apply.

For the iron ore industry, the product development function is divided into the following components:

1) Collection of information (input) from customer, market benchmarking activities, etc.

2) Determination of technical specification based on the information (input) obtained.

3) Establishment of a product development plan.

4) Plan implementation.

5) Verification of the new product performance used by the customer.

6) Validation of the new product performance used by the customer.

A contract review (see 4.3) should be made for new or modified product.

4.5 Document and data control

INTENT To ensure that only current editions of policies and procedures are used in producing and evaluating the product.

GUIDELINES Control means review and approval before issue. Responsibility should be specified for issuing, changing, and recording changes to, controlled documents. Documents considered controlled should be listed and the method used to perform the control specified. The easiest way to do this is with a matrix, listing documents on the vertical and the control elements on the horizontal. Up-to-date copies of all documents and procedures relevant to a work area should be readily available at work stations. Obsolete documents should be promptly removed from points of issue and use or be marked "obsolete document not intended for use in the process control." Changes should go through the same approval process as the original document. The nature of the changes should be identified and a master list of changes should be established. After a reasonable number of changes, a new document should be issued.

Documents should have titles, issue dates, revision numbers, authorizing signatures, and a clear distribution list. Changes made in the document should be highlighted where practical. The retrieval of obsolete documents should be based on the distribution list.

Examples of what could be considered controlled documents are; all quality plans and manuals, calibration and operating procedures and records, purchase orders, specifications, statistical process control, charts, etc.; in short all documents whose contents have a bearing on the quality of the final product.

4.6 Purchasing

INTENT To ensure that purchased products meet required specifications.

GUIDELINES Although you may want to include other materials, the standard is only concerned with those materials that are purchased and become part of the product for resale, i.e., bentonite in iron ore pellets, coal or coke breeze in iron ore pellets, etc.

Responsibility for evaluation of suppliers and the procurement of conforming materials should be specified. The procedure should have three sections describing; assessment of suppliers, the technical requirements to be included with the purchase order and the method by which these requirements will be verified. An approved suppliers list is required, as well as the criteria for approval of a supplier. Supplier approval criteria can be different for different suppliers and supplier approval can be based on previous experience, but this must be documented. Purchase orders should provide the necessary specification information. The procedure with respect

to substitutions should be specified. Corrective action with respect to suppliers who do not meet requirements should be addressed. The procedure should specify which purchasing records are kept, where and for how long. You should be allowed to conduct source inspection at your supplier's premises, i.e., supplier audits.

Note that obtaining a certificate of conformity or certificate of analysis of the product from a supplier is not in itself sufficient evidence of satisfactory material quality. The certificate has no meaning unless you have carried out an adequate way to be confident of the supplier's product quality. This may be accomplished through methods such as assessment or audits.

4.7 Control of customer-supplied product

This is material supplied by your customer that is used in producing a product that is returned to your customer.

INTENT To ensure that material supplied by the customer meets the requirements of the end product.

GUIDELINES The requirements of this clause are similar to those under 4.6 but are specifically directed at verifying that all products supplied by the customer meet required specifications. If you need to have a procedure to cover this element of the standard, requirements are similar to those for purchased product but there will be additional requirements. Responsibility for control of customer-supplied product should be specified. The customer should be informed of noncomformities in supplied products. Customer-supplied products should be protected and identified while in process. This is generally an exception in the iron ore industry.

4.8 Product identification and traceability

INTENT To ensure positive product identification and traceability from receipt through production to time of shipment.

GUIDELINES Traceability in the iron ore industry is difficult and is not mandatory unless required by contract. Where traceability is required you need to specify who ensures traceability of individual product to the applicable specification, product should be identified from receipt through shipping and this needs to be recorded. This element could be combined with test status and relabelled product identification and test status, however, it is best to keep separately when possible.

4.9 Process control

INTENT To ensure that production processes are planned and operated under the specified, controlled conditions. This includes preventive maintenance of all equipment that affects process capability.

GUIDELINES Process control is the key operating element of the quality system. The procedure should demonstrate that true control is the intent and not just record keeping. Can you demonstrate response to a process that is going beyond the specification or control limits?

Build your process control procedures around the methods used to control the operation from mining through shipping. The procedures should be very clear on who has what responsibility for process operation, how and by whom the process is monitored and where the results are recorded. The monitoring methods used for quality control and the acceptance criteria for a product should be defined. The method of approving changes to a process or approval of a new process should be specified. You should also include examples of all forms used in controlling the process (statistical process control) charts, sample results, etc.

Use the tiered approach described earlier (4.2.3) and put the Standard Operating Procedures (SOPs) in a separate document that is referenced from the quality manual. The SOPs should be developed to tie in with the process control elements and the key control points in the quality plan. They support the process control elements in the quality manual and define the actions necessary to ensure that the process produces a quality product.

You may need a further level of documentation if the process is complicated. This would take the form of detailed work instructions. The SOP would then be a summary sheet of the key points in the process and the work instruction would supply the detail. The work instructions must be referenced in the appropriate area of the SOP. Any proprietary procedures would be documented in your SOP and or work instructions.

A word on preparing SOPs. Do not attempt to repeat the basic skills of the process operator's training. Any requirement for basic skills is dealt with under the section on training. There is an assumption in this section that you are writing the SOPs for a trained operator who has a general familiarity with the equipment and the process. You do not need to specify how to start and run the machine, only specify those aspects of the job that ensure that the processes are carried out under the specified conditions of control. An analogy would be a procedure for changing a flat tyre. You can assume that the operator knows how to operate the jack!

You must also cross-reference your preventive maintenance system for all equipment identified as affecting process capability.

Special processes

INTENT To ensure control of processes where the quality of the product cannot be definitively verified by subsequent inspection and testing and where, for example, deficiencies may only become apparent when the product is in use.

GUIDELINES The requirement for special processes is similar to process control but because product quality cannot be verified by definitive tests on the final product, more emphasis is placed on process control than in the case of a product that can be definitively tested after it is made. For special processes, you should specify who is responsible for the preparation and approval of procedures, deciding what control equipment and personnel are required, and for monitoring processes and maintaining records. Continuous in-process monitoring and compliance with documented procedures are

required to ensure that specified requirements are met. The procedure must specify how effectiveness of the process in producing the specified results is confirmed. Responsibility for maintenance of the equipment must be stated. Required action must be specified for unauthorized deviation from approved procedures and it must be clear who can authorize a deviation. This element may be excepted in the iron ore industry.

4. 10 Inspection and testing

INTENT To ensure sufficient inspection and testing is carried out to establish conformity of process and product. The procedure on inspection and testing is closely tied to the quality plan.

GUIDELINES This clause covers the activities used to verify conformity of product and it is recommended to use the term sampling because inspection is a manufacturing term. The standard specifies three levels of sampling and testing; receiving, in-process and final. **Product therefore means raw materials, product in process as well as finished product.**

In your documentation you should make specific recommendations for each stage of sampling and testing. The methods used for sampling should be described, as well as sampling techniques, sampling frequency, action based on findings, who is responsible for response to testing results and details of record retention. The extent of the sampling and testing is your decision. On one product you may decide that checking the identity of the raw material against a purchase order is sufficient. You may on another product want to carry out extensive testing before using the material. This is your decision provided you have a documented procedure for the formal verification process.

Receiving sampling can be excepted from the miner because the material is supplied from your own source. This sampling is specific only to raw materials in your finished product, i.e., bentonite, coal, flux, etc. A system should exist whereby incoming noncomformities for these products must be segregated, flagged and dispositioned. **In-process** inspection monitoring and control are according to the quality plan. For in-process verification there is probably not much you can do other than testing samples taken at defined locations and times. Nonconforming product in process should be identified. On **finished product,** and in conjunction with shipment, it should be determined that all verification activities are complete. Records should be kept to show that verification activities are complete and that the product meets acceptance criteria.

4.11 Control of inspection, measuring and test equipment

INTENT To ensure that testing equipment used for verification (sampling, measuring and testing, etc.) is adequately maintained and calibrated.

GUIDELINES Remember the test equipment referred to here is restricted to that which is used to verify the product quality. Plant instrumentation used for observation, fault diagnosis, safety, etc., should obviously be calibrated but is exempt from ISO 9000 requirements; however if you write these items in your manual they then become part of the quality system.

The procedure on calibration should include all equipment used for testing the product as well as the measuring equipment used to control the process. Calibration should be traceable to national standards or where no national standard is available, calibration procedures based on manufacturer's recommendations or sound scientific principles are acceptable, (i.e., historical data of your own process). If equipment is found to be out of calibration it must be repaired before further use and you should specify action to be taken if the equipment cannot be repaired. You should make provision where possible for the review of past measurements if an instrument is found to be out of calibration.

The procedure should also contain statements on the working and calibration environment and protection of instruments from damage and tampering. This obviously is to be read as "within reason." If someone has to open a cabinet closed with bolts in order to tamper with the settings then this would be defined as tamper-proof. Remember ISO doesn't tell you what equipment to use or how to calibrate it. You identify the equipment that has the accuracy and precision required. You develop the calibration procedures based on your key control points identified in the quality plan.

4.12 Inspection and test status

INTENT To ensure that at the receiving, in-process and final stages of the production process, only product that has passed the tests at that stage can be used for the next stage.

GUIDELINES Test status for raw materials, in-process ore and finished product should be obvious. it is recommended that this element be combined with product identification.

4.13 Control of nonconforming product

INTENT To prevent the inadvertent use of nonconforming material or product.

NOTE: **This should be "within reason." The cost of the procedures to prevent unintended use shoud be balanced against the probability of the unintended use.**

GUIDELINES Remember that this clause applies to all nonconforming product whether it be raw material, in-process ore or finished product.

You should specify responsibility for disposition of nonconforming product and this includes noncomformities caused by suppliers. This responsibility does not have to rest with one person. Different persons can be responsible for nonconformity disposition in the mine, concentrator, pelletizing plant, etc. Nonconformity disposition affecting the finished product however should be approved by the customer unless waived by prior arrangement. Records should be kept of each nonconformity and be available for customer inspection. A form is required for nonconformity. These records of noncomformities should be filed and cross-referenced by the corrective and

preventive action procedure to ensure determination and correction of prime causes of the nonconformity. Whenever you find nonconforming product, your procedure should trigger review and disposition of the nonconformity and corrective action.

There are four possible dispositions listed in the standard:

- rework to meet specifications;
- accept by concession (with or without rework);
- re-grade for alternate use, or
- reject or scrap.

"Rework to meet specifications" would however include blending ores with nonconforming product, under procedures which ensure that the resulting mixture is in full compliance with specified requirements. This can be part of your stockpile management program.

The procedure should ensure that nonconforming product is adequately defined and how instances of nonconformity are communicated back to those producing the product. "Rework" and "accept by concession" dispositions should have high level approval so that persons making the disposition are technically competent to do so. Nonconforming product should be segregated if possible and disposed of in a rational fashion. Reworked product should be re-sampled for testing.

All noncomformities are measured against internal and external customer specifications.

4.14 Corrective and preventive action

4.1 4.1 General

INTENT To investigate the prime cause of noncomformities and initiate the corrective preventive action required to avoid recurrence thereby analysing its effectiveness. Also to prevent occurrences by focusing on potential problems and eliminating upstream noncomformities.

4.14.2 Corrective action

GUIDELINES Corrective action flow from nonconformity reviews and are an essential element of a higher level program. You should specify responsibility for initiation, follow-up and reporting of corrective action. You should maintain records of corrective action and any changes to procedures that are made as a result. Corrective action requires a form to be used for each occurrence. In some cases it is efficient to put both the nonconformity and the corrective action on one form. Whatever the method these forms become quality records when completed. A log of open corrective actions should be maintained as they tend to remain without any action being taken if there is no follow up.