TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

FINAL DRAFT
prCEN/TS 15358

September 2005

ICS 75.160.10

English Version

Solid recovered fuels - Quality management systems - Particular requirements for their application to the production of solid recovered fuels

Combustibles solides de récupération - Systémes de management de la qualité - Impositions particulières pour leur application à la production de combustibles solides de récupération

Feste Sekundärbrennstoffe - Qualitätsmanagementsysteme - Besondere Anforderungen für die Anwendung bei der Herstellung von festen Sekundärbrennstoffen

This draft Technical Specification is submitted to CEN members for formal vote. It has been drawn up by the Technical Committee CEN/TC 343.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. prCEN/TS 15358:2005: E

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Foreword

This Technical Specification (prCEN/TS 15358:2005) has been prepared by Technical Committee CEN/TC 343 “Solid recovered fuels”, the secretariat of which is held by SFS.

This Technical Specification is currently submitted to the Formal Vote.

Introduction

In the context of SRF production, the Quality Management (QM) strategy is mainly based on the fact that, by increasing knowledge about the whole production-process, it is possible to reduce the amount of sampling and testing to be carried out on the final products. This strategy is expressed by good Quality Management Procedures in the manufacturing process, including good record-keeping. In the context of SRF, Quality Management offers a route through which the confidence of customers and regulators can be established and maintained.

The goal of this Technical Specification is the development of a Quality Management System (QMS) for SRF production and trade that provides for continual improvement, emphasising the fulfilment of quality requirements.

This Technical Specification is a base for developing a QMS for a SRF supplier organization which has not earlier established a QMS. It can also be used as a supporting document for a supplier which already has a QMS established.

This Technical Specification, coupled with applicable customer-specific requirements and the normative references specified in Clause 2, defines the fundamental quality management system requirements for those subscribing to this Technical Specification. This Technical Specification is a base for developing a QMS for supplier who has not earlier established a QMS. It can also be seen as a supporting document for supplier who already has a QMS established.

The development of a quality management system for solid recovered fuels based on this TS does not involve a compulsory third party certification, however this certification is recommended.

The emphasis of this Technical Specification is on:

1) giving wider confidence to the production and trading of SRF;

2) defining the documentation to be used for internal procedures and communicating to all parties the specifications needed to ensure the achievement of the quality objectives;

3) verifying the origin and demonstrating the properties of the input materials (i.e. non hazardous wastes).

The Quality Management Systems accords with EN ISO 9001 to cover the whole process from the point of waste reception to the point of delivery of SRF to the customer. Quality Management Systems have several important features, including the definition of:

a) the key steps in the process;

b) the person(s) who is/are responsible for each step of the process, and for the overall co-ordination of quality-management;

c) training – policies and procedures for execution;

d) procedures for production;

e) procedures for record-keeping, to provide full traceability;

f) procedures for dealing with failures, and self-improvement;

g) procedures for the development of the processing.

To accomplish CEN Internal Regulations for the drafting of documents in this Technical Specification boxed text is used for the original EN ISO 9001:2000 text, while sector-specific supplemental requirements are outside the boxes.
Paragraphs marked “NOTE” are for guidance in understanding or clarifying the associated requirement.

Where the term “such as” is used, any suggestions given are for guidance only.

1 Scope

This Technical Specification specifies requirements for the quality management system for the production of solid recovered fuels from the reception of waste(s) up to the delivery of solid recovered fuels (Figure 1).

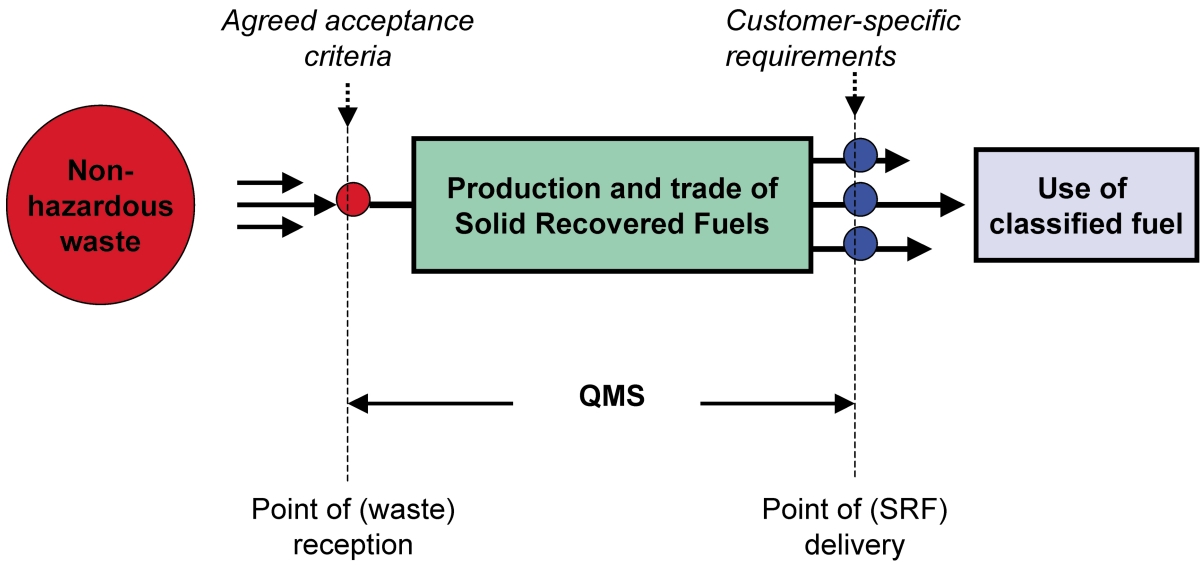

Figure 1 — Quality management systems within the solid recovered fuels chain

2 Normative references

The following referenced documents are indispensable for their application of this Technical Specification. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

prCEN/TS 15357, *Solid recovered fuels — Terminology, definitions and descriptions*

prCEN/TS 15359, *Solid recovered fuels — Specifications and classes*

prCEN/TS xxx[1)], *Solid recovered fuels — Methods for sampling*

prCEN/TS xxx[2)], *Solid recovered fuels — Methods for laboratory sample preparation*

prCEN/TS xxx[3)], *Solid recovered fuels — Method for the determination of biodegradable/biogenic material*

EN ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2000)*

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1) To be published. Registered under WI 00343028.

2 To be published. Registered under WI 00343029.

3) To be published.

3 Terms and definitions

For the purposes of this Technical Specification, the terms and definitions given in EN ISO 9000:2000, prCEN/TS 15357:2005 and the following apply.

3.1
product realization
production of solid recovered fuels

4 Quality management system

4.1 General requirements

EN ISO 9001:2000, Quality management systems – Requirements

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization,

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

The organization shall establish and maintain a programme for achieving its objectives and targets. It shall specify:

a) a designation of responsibilities to named personnel for achieving objectives and targets at each relevant function and level of the organization;

b) the means and timeframe by which they are to be achieved.

If a project relates to new developments and new or modified activities, or products or services, programme(s) shall be reviewed and amended as necessary to ensure that quality management is applied appropriately to such projects.

The organization shall establish and maintain internal procedures for defining responsibility and authority for handling and investigating non-conformity, taking action to mitigate any impacts caused and to initiate and complete corrective and preventive actions.

Any corrective or preventive action taken to eliminate the causes of actual and potential non-conformities shall be appropriate to the magnitude of the problems and commensurate with the quality impact encountered.

The organization shall implement and record any changes in the documented procedures resulting from corrective and preventive actions.

The supplier of solid recovered fuels is responsible for the conformity with the agreed specification. The quality management system shall be as comprehensive as is necessary to meet the quality objectives and shall be included in quality systems of different operators in the production chain.

The responsibility for the inputs, the partly-processed materials and/or the finished solid recovered fuels in the different parts of the production chain shall be transferred to the next operator in the chain, and eventually to the end user as soon as it has been accepted that the material correspond to the quality agreed between the parties.

4.1.1 Outsourced processes

Among the outsourced processes, the transport of input waste and of solid recovered fuels and the selection and control of laboratories for analysis should be managed according to documented procedures.

Other outsourced processes should be managed in line with in-house processes.

4.2 Documentation requirements

4.2.1 General

EN ISO 9001:2000, Quality management systems - Requirements

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

EN ISO 9001:2000, Quality management systems - Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions,

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system

The quality manual is a document prepared by the organization that systematically defines procedures needed to implement a quality management system for a solid recovered fuels supply chain.

The quality manual is a tool to demonstrate to all parties (producers, customers, authorities, other interested organizations etc.) how the requirements are fulfilled.

4.2.3 Control of documents

EN ISO 9001:2000, Quality management systems - Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

4.2.4 Control of records

EN ISO 9001:2000, Quality management systems - Requirements

4.2.4 Control of records

5 Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.Management responsibility

5.1 Management commitment

EN ISO 9001:2000, Quality management systems – Requirements

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Customer focus

EN ISO 9001:2000, Quality management systems – Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy

EN ISO 9001:2000, Quality management systems – Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

The organization's quality policy shall be available to the public.

5.4 Planning

5.4.1 Quality objectives

EN ISO 9001:2000, Quality management systems – Requirements

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)] are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

The organization shall establish and maintain the procedure(s) to identify the aspects of its activities, products or services that it can control and over which it can be expected to have an influence, so as to determine those which have or can have significant impacts on the quality.

The organization shall ensure that the aspects related to these significant impacts are considered in setting its objectives. This includes the use of the format for declaration of conformity with this Techncial Specification (prCEN/TS 15359).

The organization shall keep this information up-to-date.

5.4.1.1 Legal and other requirements

The organization shall establish and maintain a procedure to identify and provide to appropriate persons access to legal and other requirements to which the organization subscribes, that are applicable to its activities, products or services.

5.4.1.2 Objectives and targets

The organization shall establish and maintain documented objectives and targets, at each relevant function and level within the organization.

When establishing and reviewing its objectives, the organization shall consider the legal and other requirements, its significant environmental aspects if established, its technological options and its financial, operational and business requirements, and the views of interested parties.

The objectives and targets shall be consistent with the quality policy, including the commitment to the prevention of pollution.

5.4.2 Quality management system planning

EN ISO 9001:2000, Quality management systems – Requirements

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Management shall take responsibility for the quality planning of the organization. This planning should focus on defining the processes needed to meet effectively and efficiently the organization's quality objectives and requirements consistent with the strategy of the organization.

Inputs for effective and efficient planning include:

a) strategies of the organization,

b) defined organizational objectives,

c) defined needs and expectations of the customers and other interested parties,

d) evaluation of statutory and regulatory requirements,

e) evaluation of performance data of the products,

f) evaluation of performance data of processes,

g) lessons learned from previous experience,

h) indicated opportunities for improvement, and

i) related risk assessment and mitigation data.

Outputs of quality planning for the organisation should define processes required to support the realization of the products such as:

a) skills and knowledge needed by the organization,

b) responsibility and authority for implementation of process improvement plans,

c) resources needed, such as financial and infrastructure,

d) metrics for evaluating the achievement of the organization's performance improvement,

e) needs for improvement including methods and tools, and

f) needs for documentation, including records.

Management shall systematically review the outputs to ensure the effectiveness and efficiency of the processes of the organization.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

EN ISO 9001:2000, Quality management systems – Requirements

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

5.5.1.1 Responsibility for quality

Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring product quality.
Personnel responsible for product quality shall have the authority to stop production to correct quality problems.
Managers with responsibility and authority for corrective action shall be promptly informed of products or processes which do not conform to requirements.

5.5.2 Management representative

EN ISO 9001:2000, Quality management systems – Requirements

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.2.1 Customer representative

Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development.

5.5.3 Internal communication

EN ISO 9001:2000, Quality management systems – Requirements

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

EN ISO 9001:2000, Quality management systems – Requirements

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.1.1 Quality management system performance

The review process by top management shall ensure that the necessary information is collected. This review shall be documented.

The management review shall address the possible need for changes to policy, objectives and other elements of the quality management system, in the light of quality system audit results, changing circumstances, environmental legislation and requirements and the commitment to continual improvement. These reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process.

The results of these reviews shall be recorded to provide, as a minimum, evidence of the achievement of:

a) the quality objectives and

b) the satisfaction of the customer(s) with the product supplied.

5.6.2 Review input

EN ISO 9001:2000, Quality management systems – Requirements

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

EN ISO 9001:2000, Quality management systems – Requirements

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 Provision of resources

EN ISO 9001:2000, Quality management systems – Requirements

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

EN ISO 9001:2000, Quality management systems – Requirements

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

EN ISO 9001:2000, Quality management systems – Requirements

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

The organization shall identify training needs. It shall require that all personnel, whose work may create a significant impact on solid recovered fuels quality, have received appropriate training.

It shall establish and maintain procedures to make its employees or members at each relevant function and level aware of:

a) the importance of conformance with the quality policy and procedures and with the requirements of the quality management system;

b) the significant impacts, actual or potential, of their work activities and the benefits of improved personal performance;

c) their roles and responsibilities in achieving conformance with the quality policy and procedures and with the requirements of the quality management system, including emergency preparedness and response requirements;

d) the potential consequences of departure from specified operating procedures.

Personnel performing the tasks that can cause significant impacts on the quality of solid recovered fuels shall be competent in terms of their education, training and/or experience.

6.3 Infrastructure

EN ISO 9001:2000, Quality management systems – Requirements

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

Management should define the infrastructure necessary for the realisation of products while considering the needs and expectations of interested parties. The infrastructure includes resources such as plant, workspace, tools and equipment, support services, information and communication technology and transport facilities.

The process to define the infrastructure necessary for achieving effective and efficient product realization should include the following:

a) provision of an infrastructure, defined in terms such as objectives, function, performance, availability, cost, health and safety, security and renewal;

b) development and implementation of maintenance methods to ensure that the infrastructure continues to meet the organization's needs; these methods should consider the type and frequency of maintenance and verification of operation of each infrastructure element, based on its criticality and usage;

c) evaluation of the infrastructure against the needs and expectations of interested parties;

d) consideration of environmental issues associated with infrastructure, such as conservation, pollution, waste and recycling.

Natural phenomena that cannot be controlled can affect the infrastructure. The plan for the infrastructure should consider the identification and mitigation of associated risks and should include strategies to protect the interests of interested parties.

6.4 Work environment

EN ISO 9001:2000, Quality management systems – Requirements

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

7 Product realization

7.1 Planning of product realization

EN ISO 9001:2000, Quality management systems – Requirements

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

NOTE 3 Product acceptance criteria should be defined and agreed by the customer and the producer using specifications and classification system defined in prCEN/TS 15359.

7.1.1 Product and process validation

Management should ensure that when validation activities are carried out such validation of products should demonstrate that the SRF meets the needs of customers Validation activities could include modelling, simulation and trials, as well as reviews involving customers.

7.1.2 Control of changes

The organization shall have a process to control and react to changes that can affect product realisation.
The effects of any change, including changes such as those induced by:

a) variability of some incoming waste (composition, structure of deliveries, new suppliers etc.);

b) availability of waste streams

shall be assessed and verification and validation activities shall be defined, to ensure compliance with customers' requirements.

Changes should be identified, recorded, evaluated, reviewed and controlled to derive an understanding of the effect on other processes and the needs of customers.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

EN ISO 9001:2000, Quality management systems – Requirements

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

Requirements for solid recovered fuels shall be stated in accordance with prCEN/TS 15359.

Conformity with item c) includes all applicable government, health and safety and environmental regulations, applied to reception, storage, handling, recycling, recovery or disposal of incoming waste and solid recovered fuels.

7.2.2 Review of requirements related to the product

EN ISO 9001:2000, Quality management systems – Requirements

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

Any waiver of the requirement stated in 7.2.2 for a formal review shall require the authorisation of the customer.

7.2.3 Customer communication

EN ISO 9001:2000, Quality management systems – Requirements

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

The organization shall establish and maintain procedures for receiving, documenting and responding to relevant communication from external interested parties (customer, authorities, other interested organizations etc.).

The organization should consider processes for external communication on its significant environmental aspects and record its decision.

7.3 Design and development

The requirements of 7.3 include product and manufacturing process design and development and focus on error prevention rather than detection. These requirements may be excluded provided that such exclusions do

not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

7.3.1 Design and development planning

EN ISO 9001:2000, Quality management systems – Requirements

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development inputs

EN ISO 9001:2000, Quality management systems – Requirements

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

The organization should identify process inputs that affect the design and development of products and facilitate effective and efficient process performance in order to satisfy the needs and expectations of customers, and those of other interested parties.

These external needs and expectations, coupled with those internal to the organization, should be suitable for translation into input requirements for the design and development processes.

Examples are as follows:

a) External inputs such as:

— customer or marketplace or other interested parties needs and expectations, and

— suppliers' and users' contributions.

b) Internal inputs such as:

— policies and objectives,

— needs and expectations of people in the organization,

— technological developments,

— competence requirements for people performing design and development,

— feedback information from past experience,

— records and data on existing processes and products, and

— outputs from other processes.

c) Inputs that identify those characteristics of processes or products that are crucial to safe and proper functioning and maintenance, such as:

- operation, installation and application,

- storage, handling and delivery,

- physical parameters and the environment, and

- requirements for treatment of the products.

Product-related inputs based on an appreciation of the needs and expectations of end users, as well as those of the direct customer, can be important. Such inputs should be formulated in a way that permits the product to be verified and validated effectively and efficiently.

7.3.3 Design and development outputs

EN ISO 9001:2000, Quality management systems – Requirements

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use

The output should include information to enable verification and validation to planned requirements.

Examples of the output of design and development include:

- data demonstrating the comparison of process inputs to process outputs,
- product specifications, including acceptance criteria,
- process specifications,
- material specifications,
- testing specifications,
- training requirements,
- user and consumer information,
- purchase requirements, and
- reports of qualification tests.

Design and development outputs should be reviewed against inputs to provide objective evidence that outputs have effectively and efficiently met the requirements for the process and product.

7.3.4 Design and development review

EN ISO 9001:2000, Quality management systems – Requirements

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5 Design and development verification

EN ISO 9001:2000, Quality management systems – Requirements

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

EN ISO 9001:2000, Quality management systems – Requirements

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7 Control of design and development changes

EN ISO 9001:2000, Quality management systems – Requirements

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

EN ISO 9001:2000, Quality management systems – Requirements

7.4.Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply products in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4)

NOTE 1 For the purposes of this Technical Specification, the items to be considered in the purchasing process are mainly incoming waste, machinery and laboratory services.

NOTE 2 The waste provider is considered a supplier.

7.4.1.1 Regulatory conformity

All purchased products or other materials used in products shall conform to applicable regulatory requirements.

Moreover only waste that can be classified as non-hazardous, according to legislation in force, shall be purchased.

7.4.1.2 Supplier quality management system development

The organization shall have a process to assure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods:

— receipt of, and evaluation of, statistical data by the organization;

— receiving inspection and/or testing;

— second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product quality.

Moreover the organization shall perform specific activities to ensure the required quality of input materials and to encourage the suppliers' quality management system development with the goal of supplier conformity with this Technical Specification. Conformity with EN ISO 9001:2000 is the first step in achieving this goal.

NOTE 1 The prioritisation of suppliers for development depends upon, for example, the supplier's quality performance and the importance of the product supplied.

NOTE 2 The application of specific activities is not required for products supplied by organizations that are, unless otherwise specified by the customer, third party registered to EN ISO 9001:2000 or other certified quality management system.

7.4.1.3 Supplier monitoring

Supplier performance shall be monitored through the following indicators:

— delivered product quality;

— customer disruptions including field returns;

— delivery schedule performance;

— special status customer notifications related to quality or delivery issues.

The organization should promote monitoring by suppliers of the performance of their manufacturing processes.

7.4.1.4 Customer-approved sources

Where specified by the contract, the organization shall purchase products, materials or services from approved sources.

The use of customer-designated sources does not relieve the organization of the responsibility for ensuring the quality of purchased products.

7.4.2 Purchasing information

EN ISO 9001:2000, Quality management systems – Requirements

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

EN ISO 9001:2000, Quality management systems – Requirements

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.4.3.1 Criteria for the acceptance of waste (as a purchased product)

7.4.3.1.1 Basic characterisation

Basic characterisation is required for each type of waste and is the first step in the acceptance procedure. It constitutes a gathering of all of the necessary information for a safe treatment of the waste.

Functions of basic characterisation

a) Basic information on the waste (e.g. type, origin and properties);

b) basic information for understanding the behaviour of waste in the line for production of SRF to choose options for treatment

Fundamental requirements for basic characterisation of the waste

a) Source and origin of the waste;

b) information on the process producing the waste;

c) data on the composition of the waste (main materials: e.g. wood, plastics);

d) appearance of the waste (e.g. physical form);

e) code according to the European Waste List (see Bibliography [1] [2] [3] [4]);

f) in case of mirror entries within the European Waste List: declaration from the waste supplier that the waste does not fall under the relevant hazard properties according to Annex III to Council Directive 91/689/EEC of 12 December 1991 on hazardous waste (see Bibliography [5]);

g) if necessary, additional precautions to be taken at the plant;

h) chemical analysis (if possible, depending on the homogeneity of the waste and if necessary, depending on the production criteria).

If the basic characterisation of waste shows that the waste fulfils the proposed criteria, the waste is deemed to be acceptable at the plant. If this is not the case, the waste is not acceptable at the plant. The producer of the waste or, in default, the person responsible for its management, is responsible for ensuring that the characterisation information is correct.

7.4.3.1.2 Compliance verification

When waste has been deemed acceptable for the SRF production plant on the basis of a basic characterisation, it shall subsequently be subject to a compliance verification plan to determine if it complies with the basic characterisation and the relevant acceptance criteria (if such acceptance criteria have been laid down).

The function of compliance verification is to check the waste streams periodically. The relevant properties to be checked are determined through the basic characterisation. The tests used for compliance verification shall be selected amongst those used in the basic characterisation. For this purpose standardised methods shall be used.

Compliance verification shall be carried out at least once a year and the operator must, in any event, ensure that compliance verification is carried out in the scope and frequency determined by basic characterisation.

7.4.3.1.3 On-site verification

Each load of waste delivered to the plant shall be visually inspected before and/or after unloading. The required documentation shall be checked.

The waste may be accepted at the plant, if it complies with the acceptance criteria as defined in the characterisation procedure. If this is not the case, the waste shall not be accepted for SRF production.

7.5 Production and service provision

7.5.1 Control of production and service provision

EN ISO 9001:2000, Quality management systems – Requirements

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions.

Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

7.5.1.1 Work instructions

The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. These instructions shall be accessible for use at the work station and shall be derived from sources such as the quality plan, the control plan and the product realization process.

7.5.1.2 Preventive and predictive maintenance

The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system.

As a minimum, this system should include the following:

— list of equipment;

— planned maintenance activities including a list of equipment and/or systems needing periodic maintenance, testing, or inspection, and the schedule for such;

— description of how inspections and periodic preventive maintenance procedures will be performed and documented;

— description of how re-inspections will be performed and effectiveness of corrective actions;

— packaging and preservation of equipment, tooling and gauging;

— availability of replacement parts for key manufacturing equipment.

The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.

7.5.2 Validation of processes for production and service provision

EN ISO 9001:2000, Quality management systems – Requirements

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4), and

e) revalidation.

7.5.3 Identification and traceability

EN ISO 9001:2000, Quality management systems – Requirements

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product(see 4.2.4).
NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.4 Customer property

EN ISO 9001:2000, Quality management systems – Requirements

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

7.5.5 Preservation of product

EN ISO 9001:2000, Quality management systems – Requirements

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.5.5.1 Storage

When appropriate, in order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals.

7.6 Control of monitoring and measuring devices

EN ISO 9001:2000, Quality management systems – Requirements

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

7.6.1 Measurement system analysis

Statistical studies should be conducted to analyse the variation present in the results of each type of measuring and test equipment system.

7.6.2 Calibration/verification records

Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to specifications, including employee- and customer-owned equipment, shall include:

— equipment identification, including the measurement standard against which the equipment is calibrated,

— revisions following engineering changes,

— any out-of-specification readings as received for calibration/verification,

— an assessment of the impact of out-of-specification condition,

— statements of conformity to specification after calibration/verification, and

— notification to the customer if suspect product or material has been shipped.

7.6.3 Laboratory/sampling requirements

7.6.3.1 Internal laboratory/sampling

An organization's internal laboratory and/or sampling facility shall have a defined scope that includes its capability to perform the required inspection, sampling, analysis, test or calibration services. This scope shall be included in the quality management system documentation. The organization shall specify and implement, as a minimum, technical requirements for:

— adequacy of the laboratory procedures,

— competency of the laboratory personnel,

— testing of the product,

— capability to perform these services correctly, traceable to the relevant process standard (such as EN, ISO, ASTM etc.),

— review of the related records, and

— competency of the operators or sampling personnel.

NOTE Accreditation to EN ISO/IEC 17025 [7] may be used to demonstrate supplier in-house laboratory conformity to this requirement but it is not mandatory.

7.6.3.2 External laboratory/inspection company

External/commercial/independent laboratory facilities or inspection companies used for inspection, sampling, analysis, test or calibration services by the organization shall have a defined scope that includes the capability to perform the required inspection, sampling, analysis test or calibration, and either

— the inspection company shall be accredited to EN ISO/IEC 17020 or national equivalent

or

— the laboratory shall be accredited to EN ISO/IEC 17025 or national equivalent.

NOTE 1 Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of EN ISO/IEC 17025 or national equivalent.

NOTE 2 When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, the organization should ensure that the requirements listed in 7.6.3.1 have been met.

8 Measurement, analysis and improvement

8.1 General

EN ISO 9001:2000, Quality management systems – Requirements

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

NOTE The conformity of the product (i.e. solid recovered fuel) with CEN/TC 343's appropriate Technical Specification shall be demonstrated.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

EN ISO 9001:2000, Quality management systems – Requirements

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

8.2.2 Internal audit

EN ISO 9001:2000, Quality management systems – Requirements

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See EN ISO 19011:2003 for guidance[8].

8.2.2.1 Quality management system audit

The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements.

8.2.2.2 Manufacturing process audit

The organization shall audit each manufacturing process to determine its effectiveness.

8.2.2.3 Product audit

The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, at a defined frequency.

8.2.2.4 Internal audit plans

Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan.

When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased.

NOTE Specific checklists should be used for each audit.

8.2.2.5 Internal auditor qualification

The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specification (see 6.2.2.2).

8.2.3 Monitoring and measurement of processes

EN ISO 9001:2000, Quality management systems – Requirements

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.3.1 Monitoring and measurement of manufacturing processes

The organization shall establish and maintain documented procedures to monitor and measure, on a regular basis, the key characteristics of its operations and activities that can have a significant impact on the product quality. This shall include the recording of information to track performance, relevant operational controls and conformance with the organization's quality objectives and targets.

The organization shall establish and maintain a documented procedure for periodically evaluating compliance with relevant legislation and regulations.

8.2.4 Monitoring and measurement of product

EN ISO 9001:2000, Quality management systems – Requirements

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.

This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

The organization should establish and specify the measurement requirements (including acceptance criteria) for its products. The organization shall plan and perform the monitoring and measurement of products to verify that the requirements of interested parties have been achieved, and to improve the production processes.

To classify and specify its product, the organization shall adhere to the rules for conformity defined by prCEN/TS 15359.

This implies the necessity to:

a) take increments and to constitute samples according to Technical Specifications dealing with sampling and sample-preparation and

b) check the quality of the product according to Technical Specifications listed in Clause 2.

Thus, the organization shall prepare, implement and improve a quality-plan for each product; this will include a sampling-plan to take into account the key steps in the production process, so as to generate sufficient data to allow the process to be kept under control, in order to fulfill the quality requirements and to engender confidence in the quality of SRF. The inherent sources of variance and uncertainties therein, including those associated with sampling and testing, shall be used to select the points in the process, and the levels of frequency, at which to take and test samples (i.e. quality-control). The quality-plan and every modification of it shall be made available on request to the authority and concerned parties, provided that confidential information remain protected.

This procedure will also allow the organization to enhance its ability to fulfil quality requirements (i.e. quality improvement).

8.2.4.1 Sampling and test methods

Sampling, sample reduction, sample preparation and testing shall be done according to Technical Specifications listed in Clause 2.

8.3 Control of nonconforming product

EN ISO 9001:2000, Quality management systems – Requirements

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

Product with unidentified or suspect status shall be first considered as nonconforming product (see 7.5.3) until tested in order to identify its real status

8.3.1 Control of reworked product

Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel.

8.3.2 Customer information

Customers shall be informed promptly in the event that nonconforming product has been shipped.

8.4 Analysis of data

EN ISO 9001:2000, Quality management systems – Requirements

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

b) conformity to product requirements (see 7.2.1),

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

Analysis of data should include the following steps:

a) data review;

b) data verification;

c) data validation.

a) Data review

Data review is an in-house examination to ensure that the data will be recorded, transmitted, and processed correctly. That includes, for example, checking for data entry, transcription, calculation, reduction, and transformation errors. It may also mean ensuring that there is a complete list of sample information available, such as blanks, duplicates, shipping dates, holding times etc. and ensuring that there are no programming errors. It is also a completeness check to determine if there are any deficiencies, such as data missing or integrity lost (for example, due to corruption or loss in storage or processing).

b) Data verification

Data verification is a process for evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual specifications

It essentially evaluates performance against pre-determined specifications, for example, in an analytical method, or a software or hardware operations system.

c) Data validation

Data validation is an analytical- and sample-specific process that extends the evaluation of data beyond method, procedure, or contractual compliance (i.e. data verification) to determine the quality of a specific data set relative to the end use.

Data verification is generally done first, internally by those generating the data or by an organization external to that group. Data validation is generally performed on the verified data later in the process and by someone independent or external to the data generator and the data user.

8.5 Improvement

8.5.1 Continual improvement

EN ISO 9001:2000, Quality management systems – Requirements

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.1.1 Continual improvement of the organization

The organization shall define a process for continual improvement (see examples in Annex B of EN ISO 9004:2000 [10]).

8.5.1.2 Manufacturing process improvement

Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters.

NOTE 1 Controlled characteristics are documented in the control plan.

NOTE 2 Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.

8.5.2 Corrective action

EN ISO 9001:2000, Quality management systems – Requirements

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (see 4.2.4), and

f) reviewing corrective action taken.

8.5.2.1 Problem solving

The organization shall have a defined process for problem solving leading to root cause identification and elimination.

If a customer-prescribed problem-solving format exists, the organization shall use the prescribed format.

8.5.2.2 Error-proofing

The organization shall use error-proofing methods in their corrective action process.

8.5.2.3 Corrective action impact

The organization shall apply to other similar processes and products the corrective action, and controls implemented, to eliminate the cause of nonconformity.

8.5.2.4 Rejected product test/analysis

The organization shall analyse product rejected by the customer.

The organization shall minimize the cycle time of this process. Records of these analyses shall be kept and made available upon request. The organization shall perform analysis and initiate corrective action to prevent recurrence.

NOTE Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action and monitoring the effectiveness of implementation.

8.5.3 Preventive action

EN ISO 9001:2000, Quality management systems – Requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken (see 4.2.4), and

e) reviewing preventive action taken.

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