English translation

Date June 2021

GASTEC QA

GENERAL REQUIREMENTS

Trust
Quality
Progress

Foreword Kiwa

This GASTEC QA General requirements (Dutch version) will be used by Kiwa Nederland BV in conjunction with the GASTEC QA approval requirements in which the product requirements are laid down and the KIWA regulations for certification.

This approval requirement is a translation from the Dutch validated version and can only be used as a supporting document.

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1 Introduction

1.1 General

The general requirements recorded in this document, along with the technical requirements, described in the GASTEC QA approval requirements are applied by Kiwa during initial assessment and perpetuation of the GASTEC QA product certificate.

List of changes:

- The word ‘IQC’ (internal quality control system) is changed to quality plan
- Definitions of certificate holder, producer, third party and supplier are recorded
- Definitions of certification staff is recorded
- Definitions of quality management system and quality plan is recorded
- Requirements of FMEA are included in annex A
- Requirements of the management of complains are included in annex B
- List of reference documents is adapted

2 Definitions

The following definitions are applicable in these general requirements:

Approval requirements: The certification requirements agreed upon and established by the Board of Experts.

Board of Experts: The GASTEC QA Board of Experts.

Audit: A systematic approval with the following purpose:

- Check whether the requirements set are continuously being met;
- Verification if correct use is made of the certificate, the certification mark and, where applicable, the associated logos and labels.

The certification mark/product certificate: A protected brand or logo, the use of which is permitted with the authorization of Kiwa to the certificate holder, in whose product upon delivery there is a legitimate confidence that it meets the requirements set out in the certification scheme declared applicable by Kiwa for product certification.

The certificate holder: The certificate holder is the legal entity that has entered into the certification agreement with Kiwa. The certificate holder does not need to be the producer.

Manufacturer: The party responsible for manufacture of the product, whether or not as the certificate holder.

Third party: Producer or supplier of a semi-finished product.

Supplier: The supplier is a legal entity who supplies the product to the purchaser. The supplier does not need to be the producer and/or certificate holder

Semi-finished product: A part of the finished product what is outsourced to a third party by the certificate holder or manufacturer.

Quality management system: A management system for directing and controlling an organization. This quality management system shall at least fulfill the requirements of ISO 9001 and certified under accreditation.

Quality plan: Description of the quality checks conducted by the supplier as part of its internal quality control system.

Initial assessment: The investigation necessary in order to verify that all requirements, as specified in the approval requirement, have been fulfilled.

Inspection: The investigation conducted after certification in order to verify that the certified products consistently fulfil the requirements as specified in the approval requirement.

New product: A product for which no GASTEC QA certificate has been issued.

Existing product: A product for which a GASTEC QA certificate has been issued.

Certification assessor: An employee who is qualified to judge reviews of design documentation based on expert judgment, prepare final assessment reports, project management for initial investigations and handling of deficiencies.

Application reviewer: An employee who is qualified to judge reviews of applications.

Reviewer: An employee who is qualified to perform reviews.

Site assessor: An employee who is qualified to perform assessments of the conformity of a product, process, service, installation, design or management system based on the specific requirements set by means of audits, tests and on-site inspection. A site assessor is also qualified to handle deficiencies.

Decision maker: An employee who is qualified to take decisions for issuing and continuing a certificate and financial handling of projects.

3 Procedure for obtaining a GASTEC QA product certificate

3.1 Initial assesment

The initial assessment is conducted by Kiwa on the basis of these general requirements and the product and/ or performance requirements as defined in the GASTEC QA approval requirements. The initial assessment tests entails:

a. An investigation to assess whether the product fulfils all product and/ or performance requirements
b. An assessment of the quality plan
c. Assessment of other required procedures

Limited initial assessment can be conducted if data can be used that has been acknowledged and accepted by Kiwa (e.g. production location or a compound).

If the requestor of the certification mark submits reports that demonstrate compliance with GASTEC QA approval requirements, proof will be required that such reports have been compiled by accredited bodies in accordance with EN-ISO/IEC 17025 for laboratories, EN-ISO/IEC 17065 for certification bodies that certify products and EN-ISO/IEC 17021-1 for certification bodies that certify and audit quality management systems. Accreditation shall apply to the required test.

3.1.1 Assessment of the product

Kiwa will asses (or order the assessment of) the products for certification on the basis of the product and/or performance requirements as defined in the GASTEC QA approval requirement.

3.1.1.1 Product design risk assessment

In case of new products or the modification of existing products, a product design FMEA shall be compiled. The requirements of the FMEA for product design are included in Annex A of this general requirements.

Note:

1) this article will only apply if explicitly stipulated as such in the GASTEC QA approval requirement.
2) A risk assessment method other than FMEA can be used. This method shall clarify the degree of severity, cause and detection to determine the risk

3.1.2 Assesment of quality plan

An official shall be appointed within the organizational structure who will be charged with managing the quality management system of the manufacturer.

The manufacturer shall be in possession of, and apply, a quality plan.

The quality plan scheme shall in any case relate to:

- Supplied raw- and/or compound materials
- The manufacture process
- The final products
- The status of measuring and testing resources
- The internal handling, storage and identification and/or method of marking the status of semi-finished and end-products

Here at least the following shall be recorded:

- Monitoring aspects
- Monitoring methods used
- Monitoring frequency
- How monitoring results are recorded and saved

As part of the assessment, checks will be conducted to ensure that the quality plan is present, comprehensive, understandable and observed.

The quality plan shall provide Kiwa with sufficient confidence that the requirements defined in this document and in the relevant GASTEC QA approval requirements are met continuously.

3.1.2.1 Production process risk assesment

A manufacturing process FMEA shall be compiled for new and existing products. The quality plan aspects related to the production process shall be based on the risk assessment of the production process. The requirements of the FMEA for product design are included in Annex A of this general requirements.

Note:

1) This article will only apply if explicitly stipulated as such in the GASTEC QA approval requirement.
2) A risk assessment method other than FMEA can be used. This method shall clarify the degree of severity, cause and detection to determine the risk

3.1.3 Assesment of procedures/operation instructions

The manufacturer shall have procedures / operational instructions in place regarding:

- The handling of products with deviations
- Correcting measures if deviations are observed
- The handling of complaints about supplied products
- Management of the operational instructions and inspection forms employed
- Instructions for the packaging and sealing of products during carriage and storage

As part of the assessment, checks will be conducted to ensure that these procedures / operational instructions are in place and are being observed.

3.1.4 Further quality system requirements

The production unit of the manufacturer, where manufacturing takes place, shall be in possession of a quality management system. This quality system shall at least comply with ISO 9001 and certified by an accredited certification body. The GASTEC QA-certified product shall fall within the scope of the quality management system certification. The quality plan shall be a part of the quality management system. A third party involved in the production shall use this quality management system.

3.2 Certification

Following the initial assessment, all results will be presented to the decision maker (see paragraph 6.2). The latter will determine whether sufficient proof exists that all relevant requirements as defined in these general requirements and in the GASTEC QA approval requirement have been fulfilled, or whether additional information and/or investigation is necessary before Kiwa can grant certification.

The certificate to be issued on the basis of the GASTEC QA approval requirement and these general requirements is referred to as Kiwa product certificate. This product certificate will be valid for an indefinite period when complying with the control requirements.

4 Procedure for perpetuating a GASTEC QA product certificate

By means of product monitoring/examination and control of the quality plan, procedures, operation instructions and FMEA audits, Kiwa will determine whether the product continues to fulfil these general requirements and the requirements defined in the GASTEC QA approval requirement.

4.1 Verification of the quality plan

During the quality system audits the following aspects will be verified:

- Calibration / verification status of testing equipment;
- Verification of incoming raw materials / components;
- Inspection of final product;
- Inspection during the manufacturing process;
- Procedure for products with deviations;
- Storage and (internal) transport of product;
- Handling of complaints;

Audits will in any case refer to:

- The products and product specifications as stipulated in the certification;
- The manufacturing process of the manufacturer;
- The quality plan of the manufacturer and the results of checks conducted by the manufacturer;
- The correct method of marking the certified products;
- Compliance with required procedures;

The frequency of the audits of these aspects has been defined as minimum 2 audit visits per year.
The audits will take place at the certificate holder and, when the product is not produced at the plant of the certificate holder, at the actual producer. In this case 1 audit is performed at the certificate holder and 1 audit at the actual producer

It is possible that the certificate holder is not the producer, but outsources his production at another location. This producer is the 'actual producer'. In that case all responsibilities between the certificate holder and the actual producer are laid down in an agreement which is available for Kiwa and at least regulates:

- How the certificate holder enforces the actual producer that the product will continuously comply with the specification (s) stated in the certificate;
- That the certification mark may only be applied to the product that the actual producer delivers to the certificate holder or that is delivered directly from the actual producer on the instructions of the certificate holder;
- That Kiwa, in the event of identified shortcomings on the part of the certificate holder, may carry out all necessary activities in the context of certification of the product at the actual producer, including taking measures;
- That relevant accreditation bodies, scheme managers and Kiwa will be given the opportunity to observe the certification activities performed by Kiwa or on behalf of Kiwa.

The certificate holder may outsource parts of the production process of the product (semi-finished product) to a third party on the condition that the activities concerned take place within the quality management system and quality plan used by the certificate holder as established during the initial inspection.

The control examinations take place at the company of the certificate holder and, moreover, when the product is not manufactured in the company of the certificate holder, at the actual producer.

If there is a third party that carries out parts of the production process of the product, the inspection takes place at the certificate holder on the basis of the quality system and quality plan.

4.2 Product verification

During the audit, the Kiwa site assessor will take samples for testing by Kiwa. The type of tests and its frequency is defined in the GASTEC QA approval requirements.
The results of this product verification will be send to certificate holder..

4.3 Non-conformity identified during the audit

In case of a non-conformity identified during an audit, the procedure “handling complaints” will be followed. This procedure is described in appendix B.2.

4.4 Handling complaints

If a customer or (end) user has a complaint about a GASTEC QA certified product, he shall report this complaint to the supplier and / or certificate holder. The supplier and / or certificate holder shall deal with this complaint.

If, as a result of the complaint, the certificate holder decides to make an adjustment to the design- and / or production process of the certified product, he will notify Kiwa of this.

If Kiwa receives a complaint from a customer or (end) user about the handling of a complaint about a certified product by the supplier and / or certificate holder, Appendix B.2 will come into effect.

5 Marking

The following can be used as GASTEC QA certification markings:

5.1 Trademark

5.2 Impact mark

5.3 Wordmark

GASTEC QA

The product-specific GASTEC QA approval requirements describe detailed requirements for the markings to be applied.

6 Certifation body requirements

6.1 General

The certification body shall be accredited according to EN-ISO/IEC 17065 for these general requirements and the GASTEC QA approval requirements

6.2 Certification staff

The persons involved in certification process are:

- Certification assessor;
- Application reviewer;
- Reviewer;
- Site assessor;
- Decision maker.

6.2.1 Competency requirements

The competency requirements have been established by the Board of Experts (see below table)

	Certification assessor / Application reviewer / Reviewer	**Site assessor**	**Decision maker**
Basic competence			
Knowledge level	Bachelor degree	MBO (post-secondary vocational education)	Bachelor degree
knowledge of operational processes, competent assessment capabilities	reviewer shall have 3 years of relevant working experience with at least 1 year in the field of certification.	1 year of relevant working experience	5 years of working experience with at least 1 year in the field of certification.
Auditing skills	n/a	auditing skills training. Minimum of 4 audits with 1conducted independently under supervision	n/a
Technical competence			
	Knowledge of general requirements	knowledge of general requirements	n/a
	Knowledge of: • Gas distribution materials • Different types of products and materials used in gas distribution • How products are used • Critical system parameters and components At least 2 years of experience in the field of manufacture, testing, inspection or installation of gas distribution materials	Knowledge of: • the technology for the manufacture of products subject to inspection • how products are used • failures and malfunctions that may occur during the production process At least 1 year experience in the field of manufacture, testing inspection and/or installation, including 3 supervised audits, 1 independently performed audit or participation in a training program, comprising 3 supervised audits, 1 independently performed audit	n/a.

6.2.2 Qualifications

The qualifications of certifying persons shall be proven by means of the assessment of knowledge and ability based on the abovementioned requirements. The authority to qualify lies with the management of the certifying body

6.3 Initial assessment report

The certifying body will incorporate the findings of the initial assessment into a report. This report is subject to the following requirements:

- Comprehensiveness: the report shall offer a verdict on all the requirements defined in the approval guideline;
- Traceability: the findings on which verdicts are based shall be recorded in a retrievable way;
- Basis for decision: the adjudicator, who decides whether or not to grant certification, shall be able to base his/her decision on the findings recorded in the report

6.4 Decision on certification

The decision on whether or not certification will be granted shall be made by a qualified decision maker who has not been involved in the certification evaluation process. The decision shall recorded in a retrievable way.

6.5 Quality system inspection report

The certifying body shall monitor the observance of obligations at the site of the manufacturer and/or supplier (see chapter 4). The findings of every inspection conducted shall be recorded in a report.

6.6 Report to the Board of Experts

The certifying body will compile a report on its certification activities at least once a year. This report shall cover the following topics:

- Changes in the number of certifications (new/expired);
- Results of inspections;
- Measures enforced in case of deviations;
- Complaints received from third parties about certified products

7 List of reference documents

EN-ISO/IEC 17065: 2012	Conformity assessment - Requirements for bodies certifying products, processes and services
EN-ISO/IEC 17025: NEN-EN-ISO/IEC 17025:2018	General requirements for the competence of testing and calibration laboratories
EN-ISO/IEC 17021-1:2015	Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements
EN-ISO 9001: 2015	Quality management systems – Requirements

Annex A: Requirements of the FMEA for product design and production process

A.1 Product design FMEA

A.1.1 Product design FMEA

The design risk inventory and evaluation takes the form of a product design FMEA.
The product design FMEA and the product shall match.

A.1.1.1 set up of product design FMEA

A format for the product design FMEA is included in this appendix. A different set-up is allowed.
The general elements of the FMEA listed below shall be included in the product design FMEA.

A.1.1.2 Failure modus

The product design FMEA shall provide scope for describing the possible failure modes, the causes of the failure modes and the consequences of the failure modes for the functions of the product and its components.

A.1.1.3 Assessment of the effects of failure modus

The assessment of the severity of each failure mode is based on the multiplication of severity, probability of cause and degree of detection, where:

- Severity is linked to the described consequence of the failure mode;
- Cause is linked to the probability of failure mode due to the specific cause described;
- Detection is linked to the reliability of the described design tool;[1)]

In principle, scoring takes place on the basis of the scoring table in A.5., The applied score shall be substantiated by the certificate holder. This can be deviated from if justified. In a deviating scoring table, the score for consequences with fatal outcome shall in any case be stated under 'severity'.
For entirely new products with no experience, the probability is estimated in a documented manner based on information about comparable products or from calculations or tests.
The documentation of the use of design tools described in the FMEA shall be available for obtaining the GASTEC QA certificate

[1)] Note: The design tool is the way in which the probability of a certain failure mode is determined, so for example a (strength) calculation or a bending test. Quality checks during the production process are not a design tool.

A.1.1.4 Improvement actions

For each failure mode, the product design FMEA should allow for the naming of improvement actions, describing:

- What the improvement action entails;
- Who will implement this;
- The expected date on which the improvement was implemented;
- The expected new assessment based on severity, cause and detection;

The improvement actions described in the FMEA shall be demonstrably complied with.

A.1.2 Content of product design FMEA

The failure modes mentioned in the product design FMEA shall at least include the following design criteria and the following phases of product use:

- Program requirements;
- Product requirements from the standard;
- User requirements;
- User actions during commissioning;
- Feasibility and possible events during the production process (also at parts suppliers);
- Possible events during use;
- Possible events during product removal.;

A.1.3 Location of the product design FMEA in the organization

The content of the product design FMEA shall, as applicable to the design and use, correspond to:

- The content of assembly and / or user instructions;
- The complaints registration;
- The applicable design drawings;

Substantive changes to the assembly and / or user instructions and changes to drawings of the product shall be reflected in the design FMEA.

A.2 Production process FMEA

A.2.1 production process FMEA

The risk inventory and evaluation of the process takes the form of a process FMEA.
The production process FMEA and the process shall match.

A.2.1.1 Design of process FMEA

A format for the production process FMEA is included in this appendix. A different set-up is allowed. The general elements of the FMEA listed below shall be included in the production process FMEA.

A.2.1.2 Failure modes

The production process FMEA offers space to describe the possible failure modes, the causes of the failure modes and the consequences of the failure modes for the process steps.

A.2.1.3 Assessment of the effect of failure modes

The assessment of the severity of each failure mode is based on the multiplication of severity, probability of cause and degree of detection, where:

- Severity is linked to the described consequence of the failure mode
- Cause is linked to the probability of failure mode due to the specific cause described
- Detection is linked to the reliability of the described process control

In principle, scoring takes place on the basis of the scoring table in A.5., The applied score shall be substantiated by the certificate holder. This may be deviated from if justified. In a deviating scoring table, the score for consequences with fatal outcome shall in any case be stated under 'severity'.

A.2.1.4 Improvement actions

For each failure mode, there shall be room in the production process FMEA for naming improvement actions, describing:

- What the improvement action entails;
- Who will implement this;
- The expected date on which the improvement was implemented;
- The expected new assessment based on severity, cause and detection;

The improvement actions described in the FMEA shall be demonstrably complied with.

A.2.3 Location of the process FMEA in the organization
The content of the process FMEA should, as applicable to the process, be based on:

- The product design FMEA;
- Flow chart or other representation of the process;

In addition, where applicable, the content of the process FMEA should feed the following documents:

- The quality plan
- Internal work instructions and internal working method;
- The content of assembly and / or operating instructions;

Finally, the manufacturing process FMEA, where applicable, should be continuously fed by:

- The complaints registration;
- Substantive changes in the production process, such as the use of other types of machines or changing the assembly method;

A.3 Assessment

Tables 2 and 3 shall be used to determine the severity of an non-conformity associated with a failure mode, according to the scheme in Table 1.

Color in table 2 and 3 for abnormal failure modus	Severity of the non-conformity
In both tables 'Red'	Serious non-conformity
At one table 'Red' / both tables 'Yellow'	Non-conformity
Others	remark

Table 1: Severity of the non-conformity

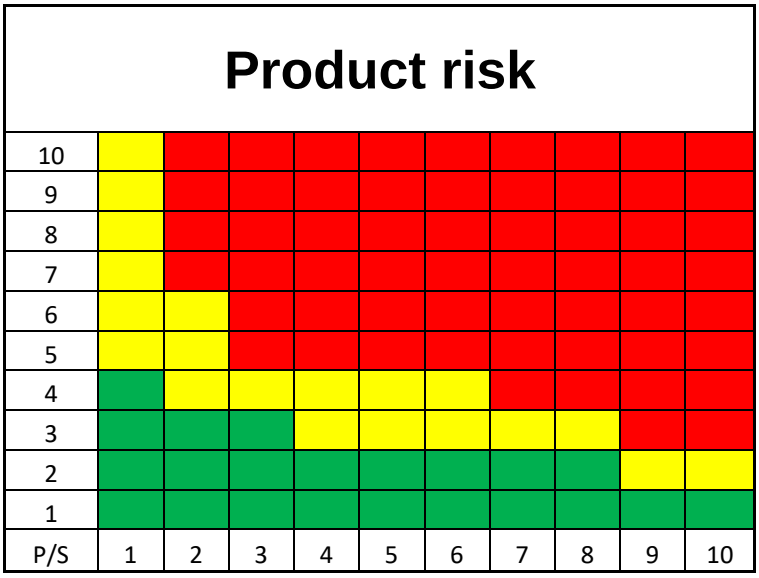

Table 2: Product risk, horizontal is 'severity-score' and vertical is 'probability-score'

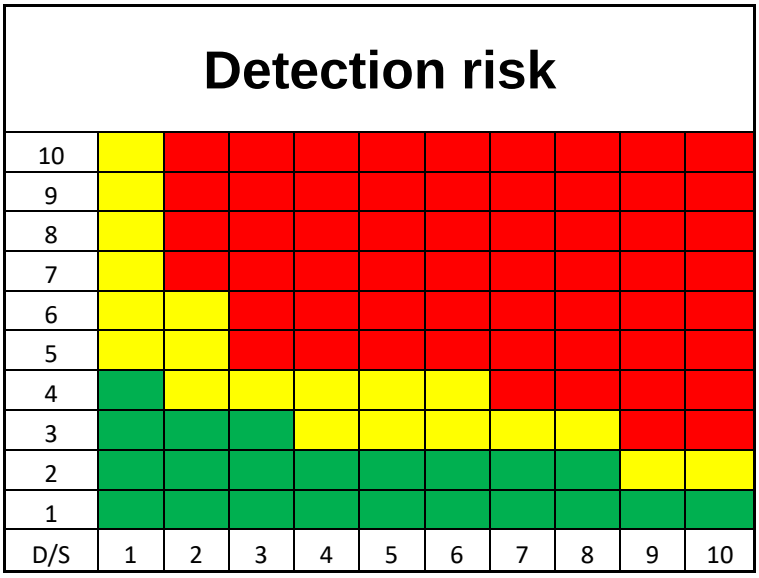

Table 3: Detection risk, horizontal is 'severity-score' and vertical is 'detection-score'

A.4 Example of FMEA

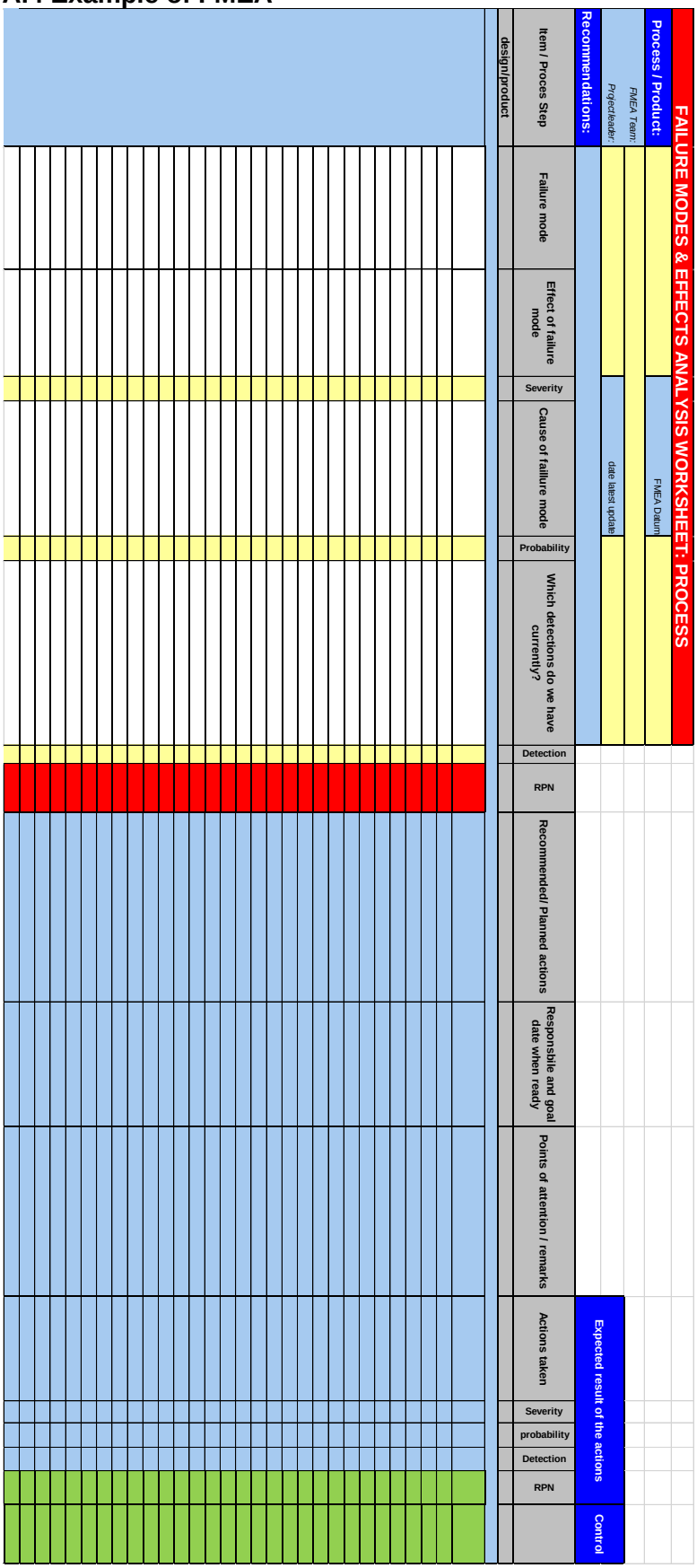

Figure 1: example of FMEA

A.5 Scoring table

FMEA weighting factors

Severity evaluation criteria

Severity	Criteria (proces)	Criteria (product)	Score
Deadly	can lead to the death of the customer or staff member without prior warning	can lead to the death of the customer or staff member without prior warning	10
Dangerously high	leads to non-compliance with legal standards and regulations and / or injury to a customer or staff member preceded by a timely warning	leads to non-compliance with legal standards and regulations and / or injury to a customer or staff member preceded by a timely warning	9
Very high	leads to the possibility that products that do not meet the requirements end up with the customer	failure will make the product defective and unusable	8
High	leads to customer dissatisfaction	leads to having to reject products already made	7
Average	cannot be corrected in the short term and leads to a long standstill of the process.	failure will render the product partially unusable or defective	6
Low	leads to having to repair products already made.	leads to customer complaints	5
Very low	can be corrected, but will lead to limited downtime of the process	can be corrected, but will result in poorer product performance	4
Minimal	leads to annoyance, but can be remedied without significant downtime of the process.	leads to annoyance for the customer, but he can remedy it himself without compromising the performance of the product	3
Gering	The failure is not noticed and has only a minor effect on the operation of the process.	The failure is not noticed by the customer and has only a minor effect on the operation of the product	2
No failure	Is not noticed and has no consequences	Failure is not noticed by the customer and has no effect on the operation of the product.	1

Failure probability evaluation criteria

Failure probability	likely failure probability	Cpk	Score
Very high	≥ 1 in 3	< 0.33	10
Almost inevitable	1 in 3	≥ 0.33	9
High	1 in 8	≥ 0.51	8
Comparable processes who usually faile	1 in 20	≥ 0.67	7
Average	1 in 80	≥ 0.83	6
Comparable with process who sometimes faile but not to a great extent	1 in 400	≥ 1.00	5
	1 in 2,000	≥ 1.17	4
Low: comparable processes only failing occasionally	1 in 15,000	≥ 1.33	3
Very low: practial the same process who faile only occasionally	1 in 150,000	≥ 1.5	2
Almost none: Failure is unlikely. Comparable processes show no failures	≤ 1 in 1,750,000	≥ 1.67	1

Detection evaluation criteria

Detection probability	Criteria and corresponding detection methods(proces)	Criteria (Design)	Score
None	practically impossible; cannot be controlled or will not be controlled	designtool cannot or will not detect cause and failure mode or there is no design tool	10
Very unlikely	possible, but unlikely; only indirectly or accidentally	very unlikely detection of the cause and failure mode by the design tool; designtool probably doesn't match final failure mode	9
Unlikely	probably no detection; visual inspection only	unlikely detection of cause and failure mode by the design tool	8
Very small	probably no detection; double visual inspection	very small chance that the design tool will detect the cause and failure mode	7
Small	perhaps detection; control by means of continuous visualization parameters, such as SPC	small chance that the design tool will detect the cause and failure mode.	6
Average	perhaps detection; control immediately after exiting the process step	average probability that the design tool will detect the cause and failure mode	5
Average/ high	good chance of detection; failure detection in subsequent steps or (with stable processes) after checking the first product	medium to high probability that the design tool will detect the cause and failure mode	4
High	good chance of detection; failure detection in the process step or error detection in subsequent steps with certain rejection of the wrong product	there is a good chance that the design tool will detect the cause and failure mode.	3
Very high	almost certain detection; failure detection in the process step with certain rejection of error product	very high probability that the design tool will detect the cause and failure mode	2
Always	certain detection; failure cannot occur due to process / product design	the design tool will certainly detect the cause and failure mode	1

Figure 2: example of a scoring table

Annex B: Handling of non-conformities

Policy for handling non-conformities
This procedure describes the policy with regard to non-conformities that are noticed during the inspection investigation (audits or product control) or that are reported as a complaint to Kiwa Nederland BV.

B.1. Policy to be followed in the event of non-conformity found during an audit

A non-conformity during a control investigation is classified into two categories:

Non-conformity (category I):
The requirements are not met. The non-conformity has no direct influence on the quality of the end product, process or performance requirement. No (written) response from the certificate holder is required. Assessment can take place during the next regular visit.

Serious non-conformity (category II):

- The non-conformity directly affects the quality of the end product, process or performance requirement, or;
- It concerns a repeated non-conformity.

The certificate holder shall respond in writing to actions 1-8 below.

Examples of non-conformities are recorded in the table below:

Table 1: Categories of deviations per main group quality plan		
Main group	**Category**	**Deviation**
Measurement equipment and calibration	Cat. I	Incorrect use of measuring equipment. Use of measuring equipment outside the calibration period.
	Cat. II	Use of equipment where, after calibration, it appears that the non-conformity is greater than permissible without action being taken.
Raw material entry control	Cat. I	Incomplete control procedures
	Cat. II	Use of alternative materials (including raw materials) or components that directly affect the product properties and which are not included in the inspection file.
Procedures and operation instructions	Cat. I	Incomplete procedures or operation instructions
	Cat. II	Failure to comply with an established procedure.
Risk analyses	Cat I	Incomplete design- or process analyses
	Cat II	Not following the action(s) from the risk analysis of the design and /or process
Production process	Cat. I	Changes in the production process that have a minor influence on the quality of the product.
	Cat. II	Changes in the production process that have a major influence on the quality of the product.
Finished product	Cat. I	Non-conformity's that do not affect the functional properties of the product.
	Cat. II	Non-conformity's from essential product properties that affect the performance of the product in its application.
Marking	Cat. I	Incomplete marking without affecting the safe use of the product.
	Cat. II	Products incorrectly provided with GASTEC QA. Incomplete marking with consequences for the safe use of the product.
Transport (internal), storage, packaging, preservation	Cat. I	If the method of internal transport, storage, packaging or preservation has a minor influence on the quality of the product
	Cat. II	If the method of internal transport, storage, packaging or preservation has a major influence on the quality of the product
Other (Preventive actions)	Cat. I	-
	Cat. II	Failure to comply with corrective actions. Rrepetitive non-conformity's.

If non-conformities are found during the control investigation or through own detection, these are reported as non-conformity or serious non-conformity.

In the event of a serious non-conformity, the certificate holder shall take the following actions:

1. **Communication:**
   The certificate holder demonstrates that all purchasers of the product have been informed in writing about the non-conformity and how the information was provided. It is clearly indicated which product(s) are involved, what the non-conformity is and how the customers will be informed in the course of the handling of the non-conformity. (Enclose a copy of the letter or e-mail stating which follow-up actions will be taken, the request to check stocks and recommendations for the use of the product, as long as the complaint is pending)
2. **Cause analysis:**
   A root cause analysis shall show how the problem could have arisen (describe the what, who, where, when and why and show what, based on numbers, standards, manuals, procedures, risk analysis of the design process and / or production process, etc. the cause is)
3. **Size:**
   Extent of the problem, in addition to the identified problem, it also did not go well elsewhere (if it concerns a non-conformity of a single product or of an entire batch, are non-conformity's in other products detected as a result of the root cause analysis)
4. **Repetition:**
   Is it a systematic non-conformity (was the non-conformity detected again after corrective and preventive measures were taken)
5. **Corrective solution (improve, restore):**
   Demonstrate that the solution delivers the desired result and is feasible and practicable and in what time frame the solution can be implemented and implemented.
6. **Preventive solution (how will it be prevented in the future):**
   Demonstrate that the solution has the correct mechanism to detect such anomalies at an earlier stage.
7. **Operationality:**
   How it is checked that the solution to the problem works in practice
8. **Handling:**
   Demonstrate that all customers (question 1) have been informed of the solution (s) taken, the operationality and follow-up actions (taking back / replacing products). If, as a result of the non-conformity, the quality system and the risk analysis of the design process and / or production process has been adjusted, Kiwa will be informed of this in writing.

In the event of a serious non-conformity, the certificate holder shall demonstrate, within 48 hours after the notification of the non-conformity by Kiwa, that action 1 has been taken and shall show in an action plan in which ways and in what time frame action 2 - 8 will be taken.

After assessing the actions, Kiwa will inform the certificate holder in writing, stating reasons, of its decision on how the control of the solution taken and its implementation will be carried out.

In the treatment of serious abnormalities, Kiwa will internally apply the 4-eyes principle.

B.2. Policy to be followed in the event of complaints reported by the customer or (end) user.

If a non-conformity is established by the customer or (end) user of a GASTEC QA certified product, he can submit a complaint to Kiwa about the delivered product.
When submitting a complaint, the complainant shall demonstrate in writing that:

a) The certificate holder of the product has been informed of the non-conformity.
b) That it has been established in consultation with the certificate holder whether there is a safety risk for the (end) user. If no consensus is reached on this, the opinion of the complainant is leading (use can be made of Table 1 for this).
c) The product has a GASTEC QA certificate and does not meet the requirements as laid down in the relevant approval requirement and / or the specifications of the certificate holder
d) The certificate holder's installation manual has been correctly applied, if relevant

If the complainant cannot demonstrate in writing points a), b) c) and d), the complaint will not be processed.

The complaint will be handled between Kiwa and the certificate holder.

If Kiwa receives a complaint about a GASTEC QA certified product, the certificate holder shall be informed immediately and the certificate holder shall answer the following questions and take action:

1. **Observing:**
   Is the complaint reporter known and the complaint details complete? (Who is the complainant, when was the complaint received, why was the complaint reported and which product is the complaint about)?
2. **Acceptance:**
   Is the observed non-conformity justified, if not why not?
3. **Response:**
   Has it been established in consultation with the complainant whether there is a security risk for the (end) user (who made this determination and on the basis of what data)?
4. **Communication:**
   The certificate holder demonstrates that all purchasers of the product have been informed in writing about the non-conformity and how the information was provided. It is clearly indicated which product (s) are involved, what the non-conformity is and how the customers will be informed in the course of the handling of the non-conformity. (Enclose a copy of the letter or e-mail stating which follow-up actions will be taken, the request to check stocks and recommendations for the use of the product, as long as the complaint is pending)
5. **Cause analysis:**
   A root cause analysis shall show how the problem could have arisen (describe the what, who, where, when and why and show the cause by means of numbers, standards, manuals, procedures, FMEA, etc.)
6. **Size**
   Extent of the problem, in addition to the identified problem, it also did not go well elsewhere (if it concerns a non-conformity of a single product or of an entire batch, are non-conformity's in other products detected as a result of the root cause analysis)
7. **Repetition:**
   Is it a systematic non-conformity (was the non-conformity detected again after corrective and preventive measures were taken)
8. **Corrective solution (improve, restore):**
   Demonstrate that the solution delivers the desired result and is feasible and practicable and in what time frame the solution can be implemented.
9. **Preventive solution (how will it be prevented in the future):**
   Demonstrate that the solution has the correct mechanism to detect such anomalies at an earlier stage.
10. **Operationality:**
    How it is checked that the solution to the problem works in practice
11. **Handling:**
    Demonstrate that all customers (question 4) have been informed of the solution (s) taken, the operationality and follow-up actions (taking back / replacing products). . If, as a result of the non-conformity, the quality system and the risk analysis of the design process and / or production process has been adjusted, Kiwa will be informed of this in writing.

In the event of a security risk for the (end) user, the certificate holder shall demonstrate within 48 hours of the notification of the complaint that action 1 - 4 has been taken and show in an action plan how and in what time frame action 5 - 11 is being undertaken.

After assessing the answer, Kiwa will inform the certificate holder in writing, stating reasons, of its decision on how the control of the solution taken and its implementation will be carried out.

Kiwa will internally apply the 4-eyes principle when dealing with non-conformity's with a safety risk.

B.3 Suspension

Suspension of the certificate
In the following cases, Kiwa can suspend the GASTEC QA certificate;

- Exceeding the deadline for answering questions;
- Not taking corrective or preventive measures on time or inadequately;
- Repetition of complaint or non-conformity;

In case of suspension of the certificate, the term of suspension is 2 months. Within this period of suspension:

- The GASTEC QA certification agreement will remain in force;
- Will Kiwa supervise the solution to be taken by the certificate holder that should lead to the lifting of the suspension;
- The certificate holder may not use the certificate and may no longer deliver products bearing the GASTEC QA certification mark. Violation of this provision is considered improper use of the GASTEC QA certification mark;

If no adequate corrective and preventive solution has been taken by the certificate holder within the set period of suspension, Kiwa will withdraw the certificate. Upon withdrawal, the GASTEC QA certification agreement expires.

Kiwa reserves the right, in the event that safety is at stake and / or in order to prevent damage, to inform or publish the certificate holder's customer (s). In such cases, the certificate holder is obliged to provide Kiwa with a list of customers.

B.4. Adjustment of the approval requirements

Following a (serious) non-conformity or complaint, it may be necessary to adjust the relevant approval requirement. Kiwa will substantiate in writing whether there is reason to revise the relevant inspection requirement and report on this to the GASTEC QA board of experts.