

Rules for Certification Bodies

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Introduction

FAMI-QS certification is based on the FAMI-QS Code of Practice for Feed Additive and Premixture Operators (the 'Code'). The only valid version of the Code is the English version, published on the FAMI-QS Asbl web site (www.fami-qs.org).

FAMI-QS certification is open to any appropriately accredited certification body established worldwide, on the basis that the body is a legal entity and will be confined to declared scopes, activities and locations. The certification body is responsible for the complete execution of the assessment of an operator seeking FAMI-QS certification, including such activities as audit planning, assessment of documents, audit visit(s), reporting and certification.

A certification body may offer FAMI-QS certification alone, or certification to other quality management systems in addition.

The certification body agrees to publication of its name and address on the official FAMI-QS listing of licensed certification bodies to be found on the FAMI-QS web site. The terms 'FAMI-QS' and 'FAMI-QS Asbl' are used interchangeably in this document.

This document should be implemented as a complementary process to the document "Rules for Operators".

1. Assessment and recognition of certification bodies by FAMI-QS Asbl

Certification bodies wishing to obtain the licence to carry out FAMI-QS certification shall apply to the FAMI-QS Asbl Board, providing details for eligibility according to established selection criteria. The application form is available on the FAMI-QS website (<http://www.fami-qs.org/documents.htm>).

The certification body applies, submitting required enclosures (accreditation certificate, fields of work, list of auditors and their qualification(s), contact details, etc.). Apart from this, the certification body has to commit to include FAMI-QS in the coverage of its accreditation within one year. This commitment shall be formalised by means of a letter addressed to the FAMI-QS Board. The Board makes a(n) approval/non-approval decision within 4 months, further to recommendation by the Expert Panel. Decision is without appeal.

As an integral part of their contractual agreement with FAMI-QS Asbl, licensed certification bodies will pay an annual fee to FAMI-QS. Fees between operators and certification bodies are at the discretion of both parties.

Upon approval, the applicant certification body shall agree to contractual provisions (co-ordination, reporting and fee obligations) and shall attend a full training session of auditors provided by FAMI-QS. Fully licensed status is achieved following endorsement of the contract by the certification body and FAMI-QS. Only licensed certification bodies are entitled to certify operators according to FAMI-QS.

No certification body is allowed to grant a FAMI-QS certificate without licence from FAMI-QS Asbl. Only FAMI-QS certificates issued by licensed certification bodies will be recognised by FAMI-QS Asbl.

Once approved, the name and details of the licensed certification bodies are gathered by FAMI-QS Asbl in a public register, available via the FAMI-QS Asbl homepage.

Approval of a certification body and inclusion in the register is subject to the respect of the contractual agreement between FAMI-QS Asbl and the certification body.

In case of non-respect of contractual agreement, FAMI-QS Asbl may decide to withdraw license from the certification body, following written notification to the company.

As part of their contractual obligations, licensed certification bodies inform FAMI-QS Asbl of the name and details of the auditors they are appointing for conducting audits.

All information obtained before, during or after the assessment, including the fact that a particular certification body has applied for approval, or that an application has been deferred or rejected, will be treated in strictest confidence by FAMI-QS Asbl.

The certification body shall notify FAMI-QS of any change to information given in the application or any change in circumstances relevant to requirements for certification bodies (set out below) within 8 weeks of the change having taken place.

2. Requirements for certification bodies

The certification body shall demonstrably comply with the following requirements by providing documentation at application. The certification body shall give consent for being audited by FAMI-QS and commit to continuous co-operation with FAMI-QS.

Applicant certification bodies should be able to demonstrate:

- Formal demonstration of their competence to carry out specific conformity assessment tasks by a third-party accreditation to provide certification to the FAMI-QS Code. The third-party is preferably an accreditation body that is signatory to the multilateral agreements of EA or IAF.
- Proven commitment to ISO 19011:2002 and IAF Guidance on ISO/IEC Guide 65 and/or the IAF Mandatory Documents applicable for ISO/IEC 17021.
- Proven experience in the feed industry (already conducting HACCP based audits in the feed business, for example FAMI-QS mutually recognized schemes or official inspection of feed business operators).
- Commitment to training and co-ordination obligations established by FAMI-QS Asbl.
- Commitment to selection of competent and suitably trained auditors, and the ongoing training of auditors.
- Within a period of two years prior to the audit, the certification body may not have undertaken any consultancy and/or training activities with the company to be audited, and should demonstrably confirm this independence.

3. Requirements for auditors

The auditors shall demonstrably comply with the following requirements by providing documentation through its certification body:

- Qualification according to ISO 19011:2002
- Proven experience in the feed (already conducting HACCP based audits in the feed business, for example FAMI-QS mutually recognized schemes or official inspection of feed business operators). A minimum of 20 audits or 3 years of experience is required.
- Lead auditor training according to ISO 19011:2002
- Specifically and regularly trained by the certification body on the FAMI-QS Code
- The auditor may not, within a period of two years prior to the audit, have undertaken any consultancy and/or training activities with the company to be audited, and should demonstrably confirm this independence.

4. Assessment of operators

The certification body assesses the interested operator for compliance with FAMI-QS on the basis of initial surveillance and re-certification audits.

The certification body is not allowed to issue the certificate until the payment of the annual member fee has been done. For that reason, the auditor will ask the operator to show the payment receipt as a proof.

Once the certification body has submitted the agreed information to FAMI-QS that shows that the operator has been successfully audited and certified, the name of the operator and the address of the certified sites will then be mentioned on the FAMI-QS web site in the list of certified companies.

4.1. Evaluation of compliance with the FAMI-QS Code

The certification body will check compliance of the operator with each clause of the FAMI-QS Code of Practice. For this purpose, auditors may use the checklist provided in Annex.

In evaluating operators for compliance with the Code, auditors should use an audit schedule which includes:

- review of the implementation of corrective actions for previous non-conformities and their effectiveness;
- presentation of any organisational changes;
- evaluation of process descriptions/documentated procedures for conformity with the standard requirements;
- evaluation of practical implementation of the Code.

The commitment of top management is estimated on the strength of its understanding of the FAMI-QS Code. The level of understanding is determined in the course of a presentation by, and discussion with, top management. Any non-conformities established are to be discussed with top management and the management representative. The same applies to the agreement of the corrective action.

Documents consulted for audit purposes, including during interviews, should be identified in the audit record. Clearly identified document samples and any additional remarks are recorded to serve as a basis for evaluation of the operator by the auditor following the interviews. Only one audit record is needed when the audit is performed jointly by two or more auditors in a team.

Where auditors operate separately during an audit, each auditor shall keep his own audit record. Evaluation is undertaken on completion of separate stages or, where non-conformities are established, immediately after the assessment of the management element concerned by both auditors jointly. At the end of the assessment, the lead auditor receives the sections of the audit record completed by the co-auditor(s). There is ultimately only one audit record for each assessment.

If the auditors wish to see confidential documents such as formulas or special job processes they shall have the approval of the management representative.

4.2. Final discussion and conclusion

Non-conformities and corrective actions to be taken are documented in the action plan, and shall be signed by the lead auditor and the management representative. The management representative receives the original copy of the action plan and makes a copy for the auditor.

4.3. Audit report

A draft of the audit report should be discussed with the operator and the final audit report sent to the operator within 6 weeks of the audit. To enable FAMI-QS to monitor audits and to ensure consistency, audit results shall be supplied to FAMI-QS in a standard format, to include the number of non-conformities per section (critical, major, etc.) and a summary of observations and conclusions. The report of findings provided to FAMI-QS Asbl shall be of sufficient detail to enable an understanding of the basis for the certification decision and should include the areas covered by the assessment, the positive and negative observations made and a summary of non-conformities. In case any uncertainties regarding the quality of audit and corresponding certification exist, the Quality Manager is entitled to initiate independent parallel audits.

A format of audit report is enclosed to this document (see Annex). Certification bodies are free to use the standard format provided by FAMI-QS or another one, but the summary audit report has to include at least the information requested in Annex (with the exception of the questionnaire, which is not mandatory).

Audit reports provided to operators in the local language (not English) shall include a statement advising the operator that a summary report in English will be sent to FAMI-QS Asbl and to the operator, and that the report will be treated in strictest confidence. The contract between the certification body and the operator should include a clause specifying that this summary report is sent confidentially to FAMI-QS Asbl. This is the responsibility of the certification body. Responsibility for determining whether an operator is to be certified or not remains entirely with the certification body.

The information obtained during the audit and recorded in the audit report will remain strictly confidential and will be made available only to representatives of the certification body and FAMI-QS Asbl. Any information used for statistical evaluation shall be formulated without any relation to the operator involved.

In case of any unresolved disagreement between an operator and a recognised certification body, circumstances should be reported in writing by the operator to FAMI-QS Asbl for consideration by the FAMI-QS Board.

5. Training and coordination with FAMI-QS Asbl

In addition to supervision by the accreditation/surveillance bodies, FAMI-QS Asbl supervises the competent, uniform and complete realisation of audits through statistical and random evaluation of audit reports and annual harmonisation meetings for certification bodies.

FAMI-QS Asbl assures the co-ordination and general training of the recognised certification bodies through annual meetings. The training of auditors remains the responsibility of certification bodies. Each certification body is required to ensure that every auditor undergoes at least 2 days of ongoing relevant technical training/development per year in order to sustain professional development and knowledge of developments in quality assurance and legal obligations relating to the animal feed sector.

As an integral part of their contractual agreement with FAMI-QS Asbl, the recognised certification bodies compulsorily shall:

- participate in the annual meeting of the Recognised Certification bodies platform;
- report to the supervisory Board regarding implemented auditor training programmes, at the latest 10 working days before the above mentioned annual meeting;
- provide (under confidentiality) a copy of each audit summary report in English;
- provide bi-annual statistical report of audits carried out and certifications granted;
- report immediately to the supervisory Board any non-conformity identified in periodical auditing that leads to withdrawal of certification;
- report to the supervisory Board about interpretation and implementation issues identified in carrying out the certification.

Annex

MODEL OF AUDIT REPORT

Updated according to the new Code and Regulations

OPERATOR:

Postal address:

SITE(s) AUDITED:

Visiting address(es) :

Other areas visited:

Contact person:

Job Title:

Email:

Telephone:

Fax:

Employees feed additives:

Other Quality Systems in place:

Annual FAMI-QS fee paid on: (date)

CERTIFICATION BODY:

Name:

Lead auditor:

Other auditors:

TYPE OF AUDIT : **Initial** **Surveillance** **Re-certification**

FAMI-QS code version:

Duration of audit :

AUDIT DATE(S):

Report date:

Scope of certification

According to the Annex I of the Regulation (EC) N° 1831/2003, the scope of the certification is (mark with a cross):

1. Category: 'technological additives'Functional groups

- a) preservatives
- b) antioxidants
- c) emulsifiers
- d) stabilisers
- e) thickeners
- f) gelling agents
- g) binders
- h) substances for control of radionucleide contamination
- i) anticaking agents
- j) acidity regulators
- k) silage additives
- l) denaturants
- (m) substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action

2. Category: 'sensory additives'Functional groups

- a) colourants
 - I. substances that add or restore colour in feedingstuffs
 - II. substances which, when fed to animals, add colours to food of animal origin
 - III. substances which favourably affect the colour of ornamental fish or birds
- b) flavouring compounds

3. Category 'nutritional additives'Functional groups

- a) vitamins, pro-vitamins and chemically well-defined substances having similar effect
- b) compounds of trace elements
- c) amino acids, their salts and analogues
- d) urea and its derivatives

4. Category 'zootechnical additives'Functional groups

- a) digestibility enhancers
- b) gut flora stabilisers
- c) substances which favourably affect the environment
- d) other zootechnical additives

 Premixtures

General assessment

General comments on the management system applied by the operator and assessment of its effectiveness in terms of compliance with the requirements of the FAMI-QS Code.

- SCOPE:

. What was looked at:

. What was found:

- MANAGEMENT SYSTEM:

. What was looked at:

. What was found:

- MANAGEMENT RESPONSIBILITY:

. What was looked at:

. What was found:

- RESOURCE MANAGEMENT:

. What was looked at:

. What was found:

- PRODUCT REALISATION:

. What was looked at:

. What was found:

- SYSTEM REVIEW:

. What was looked at:

. What was found:

- CONTROL OF NONCONFORMING PRODUCTS:

. What was looked at:

. What was found:

- STATISTIC TECHNIQUES:

. What was looked at:

. What was found:

Non-conformities and recommendations**Summary**

FAMI-QS Section	Grade			
	Critical	Major	Minor	Recomm.
2- Scope				
4- Management system				
5- Management responsibility				
6- Resource management				
7- Product realisation				
8- System review				
9- Control of non-conforming products				
10- Statistic techniques				
Total amount				

Details of non-conformities/recommendations and corrective actions

N.	FAMI-QS Section	Finding	Date of finding	Grade	Corrective action	Done (date)

Questionnaire

	List other standards the operator may comply with:	Remark:		
		Yes	No	Remark
4 Management System				
4.1 General requirements				
a	Is there a documented MS in place?			
b	Does the MS include regulatory, safety and customer requirements?			
c	Does the MS cover all the operator's activities?			
d	Are there other activities that conflict with the feed safety requirements?			
4.2 Management principles				
a	Can employees commitment to feed safety and quality be demonstrated?			
b	Are HACCP principles applied?			
c	Is an effective change control system implemented?			
d	Is there a system in place to inform Management in case of threats to product quality and feed safety?			
e	Is there a system in place to ensure management is kept up-dated on all relevant legislation, feed and food safety issues and other relevant guidelines?			
4.3 General documentation requirements				
a	Does a written quality and safety policy exist?			
b	Is there a Quality Manual in place?			
c	Are documented procedures and records available?			
d	Is the scope of the MS defined?			
e	Are quality procedures established as part of the MS?			
f	Do quality procedures cover the prerequisite program in support of the HACCP program?			
g	Are HACCP procedures sufficient to ensure feed safety?			
h	Are specifications and testing procedures for incoming materials and finished products documented?			
i	Are master formulae and operating instructions for each product or group of products in place?			
j	Are Processing records for each batch of product available?			
k	Are Standard Operating Procedures (SOPs) for all activities under the scope of the MS documented?			

l	Are documents unambiguous and include title, nature and purpose?			
m	Are documents approved, signed and dated by appropriate authorised responsible person(s)?			
n	Are documents kept up to date?			
5 Management responsibility				
5.1 Management commitment				
a	Can Management commitment to feed safety and quality be demonstrated?			
5.2 Quality and Safety Policy				
a	Does the quality and safety policy specify the operator's objectives including regulatory and customer requirements?			
b	Is the policy adequately communicated?			
c	Does the operator have the basic resources necessary to fulfil the stated objectives?			
d	Are the Management and HACCP systems documented, reviewed, updated and communicated to key staff?			
5.3 Responsibility, authority and communication				
a	Is a suitably qualified HACCP team leader appointed?			
b	Is the scope of the HACCP system clearly defined?			
c	Do job descriptions exist for each individual or group of individuals?			
d	Is there a system in place to identify and correct problems within the management and HACCP systems?			
e	Is a suitably qualified person appointed to ensure compliance with regulatory requirements?			
f	Is an organisational chart available?			
5.4 Management representative				
a	Is a management representative with responsibility for quality and safety appointed?			
b	Does the management representative report to top management?			
c	Do responsibilities include promotion of awareness of customer requirements?			
5.5 Management review				
a	Is a documented procedure in place for management to review the suitability and effectiveness of the MS and HACCP?			
b	Are records of this review available?			
c	Is the review conducted periodically and predefined intervals?			
d	Are conclusions drawn and actions taken documented as part of the review?			
e	All actions communicated to key personnel within the organisation?			

6 Resource management				
6.1 Provision of resources				
a	An organisational chart exists and is updated?			
b	Appropriate persons have been assigned responsibilities to comply with external requirements?			
c	The design is appropriate?			
6.2 Human resources				
a	The staff is sufficient and skilled to comply with expected tasks and requirements?			
b	Job descriptions are available and updated?			
c	Necessary competence are available in disciplines concerning: <ul style="list-style-type: none"> - Feed safety - HACCP - Hygiene - Quality - Health and safety - Environment 			
d	Level of competence is documented and maintained?			
e	Is there a sufficient level on personnel hygiene facilities and personel hygiene?			
6.3 Infrastructure				
a	The facility is designed to facilitate a good environment as described in 6.3.2.1?			
b	The facility is designed to make it easy to clean if necessary?			
c	The facility is suitable to minimize feed safety risks?			
d	Necessary utilities are available e.g. <ul style="list-style-type: none"> - Potable water or other water quality - Steam - Pressured air - Heating system - Extraction units - Other relevant utility system 			
6.4 Maintenance and control of monitoring and measuring devices				
a	A formal calibration system is in place?			
b	This includes items to be calibrated?			
c	Appropriate calibration intervals are defined			
d	Calibration results are documented?			
e	A formal preventive maintenance system exists?			
f	Appropriate maintenance intervals are defined?			
g	Maintenance work is documented?			

h	Maintenance work does not interfere with product safety?			
6.5 Cleaning				
a	A formal cleaning program exists covering: <ul style="list-style-type: none"> - Daily house-keeping - Periodic deep cleaning - Cleaning after maintenance 			
b	The program defines responsibility?			
c	Post evaluation is covered?			
d	Cleaning records are currently filled-in?			
e	Procedures on cleaning of equipment exist and they support hygiene and feed safety?			
f	Employees are trained in cleaning procedures and the training is documented?			
6.6 Pest control				
a	A formal (documented) preventive pest control system is in place?			
b	The responsibility: In-house or contracted?			
c	Ensure that relevant preventive measures are taken, re.: <ul style="list-style-type: none"> - Rodents, outside and inside - Insects, flying and crawling - Birds - Other relevant pests 			
d	Ensure a map or schematics of preventive measures showing the locations exist and are updated?			
e	Pest activities are documented?			
f	Applied pesticides/chemicals are suitable for the purpose (Product Data Sheet)?			
g	Ensure legality of the pesticide/chemicals?			
h	The plant is maintained reasonably clear of infestation?			
6.7 Waste control				
a	Waste materials are properly identified to avoid mix-up with production materials?			
b	Waste is handled properly to avoid risks for workers or environment, both internally and externally?			
7 Product realisation				
7.1 Product requirements				
a	A system to identify external requirement is implemented?			
b	The external requirement are communicated and complied with?			
c	Requirements and compliance are documented?			
d	Requirements specified by customers are controlled and implemented?			

e	Procedures are in place to comply with identified requirements?			
f	Relevant product information is in place?			
g	The information is communicated to the customer?			
h	Information provided by customers are received and implemented?			
7.2 HACCP program				
a	A HACCP program is developed and maintained?			
b	A multidisciplinary team is announced?			
c	A competent team leader is appointed?			
d	Adequate training of the HACCP team members is supplied?			
e	An adequate prerequisite quality program exists?			
f	A HACCP analysis is performed and documented? <ul style="list-style-type: none"> - The Critical Control Points (CCPs) are identified - Critical limits are specified - Monitoring is provided - A deviation procedure is established and implemented - Verification procedures are established and implemented - All procedures and records are archived 			
g	Possible biological, physical and chemical hazards are considered			
7.3 Design and development				
a	Development plans are issued prior to relevant phases of the development process?			
b	The development plan considers risks related to safety?			
c	HACCP is considered?			
d	A formal change control procedure exists?			
e	Changes are approved before implementation?			
f	Changes are controlled and documented?			
g	Changes implemented are reviewed, verified and archived?			
h	Safety, quality and regulatory requirements are covered by the change control procedure?			
7.4 Handling of incoming materials				
a	New suppliers are covered by an approval process?			
b	Approved suppliers are documented, reviewed, re-evaluated and the documentation is up-to-date?			
c	The review is done periodically at a predetermined interval?			
d	Purchased incoming material has an agreed specification?			
e	Specifications comply with feed safety topics and legislative requirements?			
f	A written procedure on handling of incoming materials exists?			

g	Incoming materials are registered uniquely and include? - Suppliers name and lot/batch number - Operators lot/batch number - Name of material - Quantity and date of receipt - Possibly expire date			
h	Incoming bulk materials are stored according to adequate separation procedures?			
i	Materials are inspected before, during and after unloading?			
j	The inspection includes contamination, pest infestation and documentation of findings?			
k	Non-conformities are recorded?			
l	Records of inspection results are documented and archived?			
m	Incoming materials are released before use?			
n	Documentation is maintained in case a product is returned to the supplier?			
7.5 Production of finished goods				
a	Production areas are accessible to authorized personnel only?			
b	Production is run according to formal production planning?			
c	The production plan is distributed to relevant persons?			
d	Production records are kept to prove compliance with master formula?			
e	Cross-contamination is prevented or controlled?			
f	Each product has a specification, unique name and/or code?			
g	Each product has a predefined label?			
h	Finished products are clearly marked and identified?			
i	Each product has a predefined packaging instruction?			
j	The packaging process is controlled to avoid contamination and mix-up?			
k	Deliveries are inspected prior to dispatch?			
l	The inspection is documented?			
m	Non-conforming products are segregated and stored in a manner to prevent failures?			
n	Storage facilities are operated in a manner to prevent failures during handling?			
o	Storage facilities are suitable to purpose, e.g. cleanliness, ventilation, dry and temperature controlled?			
p	A defined stock rotation system is in place, e.g. FIFO?			
q	Outdated stock is controlled and segregated			
r	Loose bulk materials are controlled and segregated from other loose bulk material?			

s	A written verification procedure is in place?			
t	Verification data demonstrates that all production processes achieve planned results?			
u	Verification data demonstrates that carry over is controlled?			
v	A traceability system is in place, including tracing back from the final product through quality control data and batch records to the raw materials used and the suppliers?			
w	Deliveries can be traced to customers, including customer name, date, batch and amount?			
x	A stability program is defined and on-going?			
y	Product environment is controlled during storage to preserve conformance with quality and safety requirements?			
7.6 Transport				
a	Agreements with subcontractors are documented			
b	Selection of transporters takes into consideration their ability to fulfill the operators requirements as certified by this code?			
c	Transporters are controlled, evaluated and meet expected quality and safety requirements?			
d	Requirements in this code are applied by the operator also to transports arranged by the buyer?			
e	Procedures are in place to ensure product integrity during transport?			
f	Packaging provides adequate protection for the raw material or finished goods?			
g	Procedures are in place to control all relevant risks found in the operators HACCP?			
h	If cleaning is required the cleaning certificates shall include all relevant information needed to evaluate if the supplied container is suitable for loading?			
i	Procedures are in place to safeguard against unwanted or forbidden contaminants?			
8 System review				
8.1 General requirements				
a	Does a formal review system exist?			
b	Does the system include collection of data?			
c	Does the system include analysis of the data?			
d	Does the system include a conclusion?			
e	Does the system include actions for improvement originating from the conclusion?			
f	Are time scales for improvements defined and maintained?			

8.2 Internal audits						
a	Is a scheduled audit program in place?					
b	Are internal audits carried out?					
c	Are the scope of audits defined?					
d	Are feed safety issues included in the scope?					
e	Are the frequency of audits defined?					
f	Are auditors suitably trained?					
g	Are audits and non-conformities reported and documented?					
h	Are reports distributed to key staff?					
i	Are formal follow-up's reported?					
j	Are corrected non-conformities verified?					
9 Control of non-conforming products						
9.1 General requirements						
a	Does a formal system exist on how to handle non-conforming products?					
b	Does the procedure cover	Product identification?				
c		Documentation of non-conformities?				
d		Evaluation of root causes?				
e		Documentation of corrective actions and verification steps?				
f		Segregation, handling and assessment of non-conforming product including: Rejected Materials? Accepted Materials with restrictions? Justification of potential alternative use within feed safety requirements?				
g		Is staff aware of these procedures?				
h	Is clear marking of non-conforming product in place or another means of control?					
i	Are records of non-conformities maintained?					
9.2 Complaint handling system						
a	Does a formal customer complaint handling system exist?					
b	Is responsibility for controlling complaints defined?					
c	Does the system include sufficient customer and product information?					
d	Are the complaints evaluated according to:	Cause?				
e		Seriousness?				
f		Customer?				

g		Other relevant topics?			
h	Are complaint topics used to prevent reoccurrence?				
i	Are the related corrective actions carried through?				
j	Is feedback given to the customer?				
9.3 Recall					
a	Does a formal recall procedure exist?				
b	Is responsibility assigned to an appropriate person?				
c	Is the recall process adequately described?				
d	Does the recall procedure include handling, reassessment and/or disposal of recalled product?				
e	Are effective corrective and preventative actions implemented?				
f	Are recalls recorded?				
g	Is the recall procedure tested regularly?				
h	Are the test recalls documented?				
i	Are the outcomes of the test recalls evaluated?				
9.4 Crisis management					
	Does a crisis management procedure exist?				
	Is responsibility for notifying customers and regulatory authorities defined?				
	Is responsibility for conducting a product recall defined?				
10 Statistical techniques					
a	Are statistical techniques applied?				
b	Has the use of statistical techniques been evaluated and defined?				
c	Is an overview of each statistical technique available?				
d	Are the suitability of techniques documented?				
e	Does the operator possess the necessary statistical competencies?				