Recognition and monitoring of quality assurance programs for the manufacturing and re-manufacturing of packaging for dangerous goods

Synonyms used		
auditor	–	auditor, surveillance auditor
dangerous goods packagings	–	packagings, large packagings and intermediate bulk containers (IBC) for the transport of dangerous goods
types of dangerous goods packaging	–	packaging types, types of IBC, types of large packagings
manufacturer	–	manufacturer, remanufacturer (production site where the packaging is manufactured / reprocessed)
Manufacturing	–	manufacturing, remanufacturing
Packaging testing	–	Packaging tests according to Annex 1 of the BAM-GGR 001

According to § 8 No. 4 GGVSEB and § 6, paragraph 5, No. 1 GGVSee, the Federal Institute for materials research and testing (BAM) is responsible for the recognition and surveillance of the quality assurance programs of manufacturers of packagings for dangerous goods according to 6.1.1.4, 6.3.2.2, 6.5.4.1, 6.6.1.2 ADR / RID and 6.1.1.3. 6.3.2.2, 6.5.4.1, 6.6.1.2 IMDG-Code.

Dangerous goods packagings may be manufactured and remanufactured only with a valid recognition of the quality assurance program (QAP) by BAM.

Recognition of the QAP may be granted only upon fulfillment of the following conditions.

Derogations from the procedures described below are to be agreed in individual cases and in advance by BAM.

A.1 Minimum requirements for the quality assurance program

For the production of packagings for dangerous goods, the manufacturer has to implement a documented QSP. A suitable structure for such a QAP is specified in the table in A.8. The QAP should contain commitments on at least the following points:

- area of application
- establishment, control and revision of QAP documents and records
- Responsibilities and authorities of the management and the employees
- competence and training for the personnel
- product realization
    - procedures for design and development and for specification changes
    - Purchasing / control of incoming raw materials, closures, etc.
    - manufacturing / remanufacturing process
    - marking and identification / traceability
    - preservation of products
    - test and measuring equipment
- testing, analysis and improvement
    - surveillance and testing of dangerous goods packagings
    - control of nonconforming products
    - corrective actions

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A.2 Audits and surveillance visits

A.2.1 Initial Audit

At the initial recognition of a QAP for the production of dangerous goods packagings in a particular production site BAM - as the competent authority - will perform the first (initial) audit.

Existing certifications to ISO 16106/ISO 9001 and thereby assessed elements will be adequately addressed during the audit.

The initial audit includes

- assessment and review of the QAP, particularly in terms of compliance with the regulations on dangerous goods,
- visiting the production facilities for assessment of the production process, including the records,
- assessment of the testing facilities and the test and measuring equipment for the self-monitoring by the manufacturer,
- assessment of the implementation of the self-monitoring, in particular the packaging testing, and the review of the related work instructions and records.

At the time of the initial audit the necessary testing facilities for self-monitoring by the manufacturer must be functional. If the manufacturer does not have its own testing equipment for self-monitoring, alternative procedures applying the criteria of BAM-GGR 005 (test house recognized by BAM for the respective dangerous goods packaging types) must be agreed with BAM before the initial audit.

Application and documentation according to A.3.1 shall be submitted in advance to BAM.

The manufacturer should send to BAM photographs of the markings required under Part 6 ADR / RID and IMDG-Code respectively prior to the first delivery of the packagings, in order to obtain information on any incorrect markings.

Taking up of production of a new packaging type does not necessarily require a renewed (initial) audit. Depending on the degree of the changes, however, a renewed re-audit may be required for the new type. BAM will decide on the necessary measures for the individual cases.

A.2.2 Surveillance visits

After the initial audit by BAM a surveillance visit has to be performed at each manufacturing site once per calendar year. It is used for assessment and review of the QAP, including any changes since the initial audit or the last surveillance visit.

The surveillance visits are carried out by BAM or a surveillance body recognized by BAM. If the surveillance is performed by a surveillance body, the report of the initial audit will be made available by the manufacturer.

The surveillance visit includes:

- review of conducted trainings for the personnel involved and of the training plan
- availability of the currently valid dangerous goods regulations and relevant testing procedures, eg for the determination of material parameters
- review the documentation of the internal and external deviations occurred in dangerous goods packaging (including recalls and complaints) as well as root cause analysis and corrective action
- review of the records of the results of self-monitoring
- review of compliance with the protocol (scope and frequency)
- assessment and review of the performance of the tests and test frequencies during the production process and packaging tests on the end-product according to Annex 1 of this BAM-GGR 001 including the respective test procedures.
  With regard to the test conditions and target values, the respective approvals and test reports (of the design type testing) are to be consulted, as amended.
- assessment of the testing facilities and the testing and measuring equipment (including their calibration) for the self-monitoring by the manufacturer

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- Checking the specifications of the design type using the corresponding test reports, technical drawings etc. referred to in the approval certificate.

During the surveillance visit all the required package testing types are to assessed. Deviations from this rule must be justified.

The packaging tests during the surveillance visit are preferably to be carried out on samples of the same design type, but may also be performed at various types. In subsequent surveillance visits preferably those design types should be subjected to packaging testing that were not audited in the previous surveillance activities.

If the manufacturer does not have its own testing facilities for self-monitoring, compliance with the conditions (test houses, testing frequencies) agreed with BAM as well as the correctness and completeness of the reports should be checked within the surveillance visits.

As the minimum requirements for the surveillance visits, the contents of the surveillance protocol and the surveillance report in accordance with the respective templates have to be assessed and documented.

When surveillance visits are performed by a surveillance body recognized by BAM, a copy of the documents must be submitted to BAM by the surveillance body within eight weeks from the surveillance visit (see C.7).

A.2.3 Special rules

A.2.3.1 Surveillance by foreign competent authorities

BAM may sign agreements with foreign competent authorities or their appointed bodies on the recognition of those competent authorities or their appointed bodies as surveillance bodies.

A producer in Germany having an approval (for manufacturing dangerous goods packagings) by a foreign competent authority with which the BAM has signed an agreement on mutual recognition of surveillance and recognition of quality assurance programs, can have his QAP either monitored by this foreign authority or by BAM.

A manufacturer abroad, whose competent authority has signed with BAM an agreement for mutual recognition of surveillance and recognition of quality assurance programs, can have his QAP either monitored by this foreign authority or by BAM under the condition that he holds German approvals (for manufacturing dangerous goods packagings).

In the case of surveillance by the respective foreign competent authority the manufacturing is subject to the provisions of that authority.

The list of foreign competent authorities and appointed bodies with such agreements is published on the website of BAM.

A.2.3.2 Manufacturers abroad

BAM does not guarantee that the production of packaging for dangerous goods abroad on the basis of German type approvals is accepted by the competent authorities of the country of manufacture. Before applying for a German type approval for the first time, manufacturers abroad shall reassure with the relevant national competent authority, whether it agrees with the production according to German type approvals. If the competent authority of the country agrees, the procedures of recognition and surveillance of the quality assurance program according to BAM-GGR 001 will be applied.

A.2.3.3 Procedure for short term type approval

For the production of dangerous goods packagings on the basis of short term type approvals no auditing and surveillance of the manufacturers quality assurance program will be performed, a certificate of recognition is not granted.

After the granting of the short term approval and before the first delivery of dangerous goods packagings the manufacturer sends photographs of the markings in accordance with Part 6 ADR / RID or the IMDG Code to BAM.

A.2.3.4 Procedure for inactive manufacturing

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The surveillance visit may be suspended if the manufacturing of dangerous goods packaging is interrupted for an entire calendar year. In this case, the manufacturer reports the status of inactive manufacturing to BAM at the end of the calendar year or at the latest the following year on January 31.

On taking up of the manufacturing again, a surveillance visit is required prior to the first delivery of dangerous goods packaging.

If there is no surveillance visit performed prior to the first delivery of the reactivated manufacturing, the QApP shall be deemed not monitored. The recognition of the QSP is revoked in this case by BAM (see A.4.3).

The declaration of inactive manufacturing is possible to a maximum of 6 years. Afterwards, a surveillance visit or alternative measure agreed with BAM is required to maintain the QAP recognition.

A.2.4 Documentation of audits and surveillance visits

Templates containing the minimum information required from audits and surveillance visits are published on the website of BAM (see model templates MA.1 to MA.3).

The documentation is in German or English.

All deviations and corrective actions determined shall be documented by the assessor during the visit and the assessor shall notify the manufacturer accordingly (model template MA.4).

Audits and surveillance visits are to be evaluated negatively if serious or safety-related non-conformities (see A.2.5.1) were observed.

The original copies of the audit or surveillance records must be signed by BAM/surveillance body and the manufacturer. Copies of the documents shall be submitted to BAM - preferably electronically - within eight weeks.

If the surveillance visit carried out by a surveillance body recognized by BAM, BAM will be provided a copy of the surveillance documents by the surveillance body.

A.2.5 Handling of non-conformities

A.2.5.1 Definition of non-conformities

Non-conformities are the non-fulfillment of specified requirements or specifications.

- A non-conformity of the approved design type of a dangerous goods packaging occurs when the specifications determined by the type approval in conjunction with the design type test report are not met.

- A deviation of the QAP occurs when the QAP applied not (any longer) corresponds to the approved QAP. Requirements on the quality assurance program are defined by BAM-GGR 001 and within the certificate of recognition of the QAP.

Serious non-conformities are deviations that do not allow type approval compliant use of the packaging but that do not result in failure of the packaging. Serious non-conformities may, inter alia, be wrong dimensions / weights, incorrect UN-marking, use of non-appropriate test equipment / facilities, etc..

Safety-relevant non-conformities are deviations that might lead to failure at type approval compliant use of the packaging. Safety-relevant non-conformities are, for example, failure of the dangerous goods packaging during the packaging tests or a too high capability indicated in the UN marking.

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A.2.5.2 Non-conformities detected within the self-monitoring by the manufacturer

If non-conformities of the approved design type of a dangerous goods packaging occur within the self-monitoring by the manufacturer, the manufacturer shall take appropriate measures to restore the type approval conforming production of the dangerous goods packagings and to document these measures. If necessary, the QAP shall be revised accordingly.

A.2.5.3 Non-conformities detected during surveillance visits

Any non-conformities in general shall be treated according to A.2.4.

If there are single negative test results during the packaging tests, the assessor will decide on the procedure to be applied. Re-testing in the form of repetition of the failed packaging tests with twice the number of samples, e.g. in analogy to ISO 16104:2003, is possible.

If safety-relevant non-conformities occur during the surveillance visit, the surveillance body / the assessor shall inform BAM immediately. BAM will assign additional necessary measures, if required.

A.2.5.4 Measures of the manufacturer for safety-relevant and serious non-conformities

If there are safety-relevant and serious non-conformities the manufacturer has to ensure that

- the UN or ADR / RID marking of all affected dangerous goods packagings is made permanently irrecognisable or the affected dangerous goods packagings are destroyed;
- already delivered dangerous goods packagings are recalled and customers are informed.

Alternative solutions are to be agreed with BAM.

A.2.5.5 Measures of BAM in case of non-conformities

BAM as the competent authority may

- request additional audits or surveillance visits at the manufacturer,
- until the removal of the non-conformities order that the UN and ADR / RID marking as allowed for by the type approval may no longer be applied,
- instruct that the non-conforming dangerous goods packagings manufactured may not be delivered and the customers are to be informed respectively and that the dangerous goods packaging must be recalled.
- revoke the recognition of the QAP.

A.3 Procedures for the recognition of the QAP

A.3.1 First-time recognition of the QAP

For the initial recognition of the QAP for manufacturing / remanufacturing of dangerous goods packagings, the manufacturer / remanufacturer BAM shall submit the following documents in German or English:

a) Application for recognition of the QAP with the following information:

- name and address of manufacturer / remanufacturer (all sites/locations) incl. contact person
- proposal for a site-specific abbreviation (short cut) for use in the UN marking
- list of activities (manufacturing/remanufacturing) covered by the QAP
- list of types of dangerous goods packagings, manufacturing of which is covered by the QAP.

Model template MA.5 can be used for application.

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b) the following extracts from the documentation of the QAP:

- documented procedures for
  - dealing with design and development or changes in specification
  - dealing with non-conforming
- work instructions for
  - packaging tests including testing frequencies and photos of the testing facilities,
  - alternatively: rules for external performance of the packaging tests appointing an external body,
- examples/templates for the form of records for
  - purchasing and control of approval conforming raw materials, closures, etc,
  - results of the tests during the production process in accordance with Appendix 1 BAM-GGR 001
  - results of packaging tests on the final product in accordance with Appendix 1 BAM-GGR 001,
  - dealing with identified non-conforming products.

c) successful initial audit, which should not be older than 6 months,

d) a copy of the monitoring contract with BAM or a surveillance body recognized by BAM

e) billing address or advance payment.

NOTE: The documents referred to in a) and b) should already be available at BAM for the initial audit and therefore – as well as documentation of the initial audit according to c) as far as available – do not have to be submitted again.

In justified cases, BAM may request further documentation from the applicant.

A.3.2 Revised version of the certificate of recognition of the QAP

The application for a revision of the recognition certificates is required if within the validity period of the recognition

- the manufacturer's name changes (change of name without relocation),
- the scope of the QAP is to be extended, for example, to another type of dangerous goods packagings,
- fundamental changes to the QAP recognized by BAM shall be made.

The following documents shall be submitted in due time (see A.5):

a) application for a revised version of the certificate of recognition of the QAP with the following information:

- upon change of name of the manufacturer: (new) name and address
- at broadening the scope of the QAP: description of the changes, if necessary documentation.

b) billing address or advance payment.

If required, BAM will agree additional documents and measures in individual cases with the applicant.

A re-audit may be required.

A.3.3 Prolongation of the recognition of the QAP

For a prolongation of recognition of the QAP the following documents need to be available at BAM no later than four weeks before the end of the currently valid certificate of recognition:

a) application for the prolongation of the approval of the QAP,

b) surveillance documents since the granting of the last QAP recognition or declaration of inactive manufacturing for each calendar year in which there has been no manufacturing,

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c) documents of the QAP in accordance with section A.3.1 b) having changed since the last recognition.

In justified cases, BAM might request further documentation from the applicant.

A.4 Certificate of recognition of the QAP

A.4.1 Granting of the recognition

If the documents referred to in A.3.1, A.3.2 and A.3.3 are reviewed with satisfactory result, BAM will grant recognition of the QAP in the form of a certificate of recognition.

This recognition is further to the positive design type tests a requirement for the granting of the type approval for the manufacturing of dangerous goods packagings.

It is restricted to the name and site of the manufacturer, the short cut granted, the activities covered by the QAP and the respective dangerous goods packaging types.

The certificate of recognition will be granted with a limited validity of at maximum three years.

The validity of a revised version of the recognition assessment will remain limited only to the validity period of the original certificate recognition.

A.4.2 Validity of the certificate of recognition

The certificate of recognition is valid only for the manufacturer and as described in A.4.1. The certificate of recognition is not valid

- after expiry of the temporary limitation contained in the approval certificate,
- if the production is shifted locally and / or the manufacturer changes its name,
- if fundamental changes to the QAP recognized by the BAM are made without notice to BAM, eg when manufacturing or testing processes are sourced out.

A.4.3 Revocation of the certificate of recognition

The certificate of recognition may be revoked at any time by BAM. The manufacturer in question shall be notified, against which obligations and rules he has failed and that the recognition of the QAP will be withdrawn. He shall have the opportunity to comment.

Sufficient reasons are, for example, if

- in the context of audits and / or surveillance visits serious or safety-related non-conformities are observed,
- during a calendar year there is no surveillance visit and no declaration of inactive manufacturing,
- the obligations referenced in A.5 are violated,
- there are factual and legal changes.

From the date of effectiveness of the revocation of the recognition, the respective dangerous goods packagings may not be manufactured any longer.

A.4.4 Consequences for the type approval

Type approval is granted by BAM to a holder of the type approval and applies to the manufacturing of packaging for dangerous goods by one or more manufacturers (sites).

By revoking the QAP recognition of the manufacturer a prerequisite for type approval is no longer satisfied. As a consequence, all corresponding type approvals based on that QAP recognition are to be revoked by BAM. If further manufacturers were contained in the type approval are, a revision of the type approval may be requested liable to fees for the manufacturers with valid QSP recognition.

If a QAP recognition becomes invalid or revoked by timing, BAM will inform all holders whose type approvals are based on this QAP recognition.

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Dangerous goods packagings, which have previously been manufactured with valid QAP recognition may continue to be placed on the market and used.

A.5 Obligations of the manufacturer

A.5.1 Monitoring contract

If the annual surveillance visits are not carried out by BAM, the manufacturer is obliged to sign a monitoring contract with a surveillance body recognized by BAM monitoring and to comply with it (see model template MA.6). If the annual surveillance visits are to be carried out by BAM, a corresponding contract with BAM shall be closed.

If the monitoring contract is terminated by one of the two parties (manufacturer or surveillance body), BAM shall be informed immediately.

If the recognition of a surveillance body is revoked by BAM (see C.4.3), BAM will notify all affected manufacturers in writing. The same applies if the recognition of a surveillance body becomes invalid by timing and is not renewed (see C.4.2). The manufacturer is obliged to conclude a new monitoring contract and to inform BAM immediately.

A.5.2 Co-operation in audits and surveillance visits

The manufacturer is obliged to co-operate in audits and surveillance visits.

The employees of BAM and of the surveillance body shall be provided immediately any necessary information required to fulfill their tasks. They shall have access to estate, facility site, business premises and testing facilities as well as to the relevant documents.

The manufacturer shall provide free of charge samples for testing from the production line, in the form of retained samples or samples from stock on hand.

A.5.3 Provision of documents

Documents additionally requested by BAM from the manufacturer shall be submitted within eight weeks.

A.5.4 Application of the approved QAP and self-monitoring

Der Hersteller hat das QSP nach erfolgter Anerkennung durch die BAM anzuwenden, die Eigenüberwachung mit dafür geeigneten Prüfeinrichtungen sowie Prüf- und Messmitteln vorzunehmen und die erforderliche Dokumentation zu führen (siehe auch 6.1.5.1.3, 6.3.5.1.3, 6.6.5.1.3 ADR/RID bzw. IMDG-Code).

After recognition by BAM, the manufacturer shall apply the QSP, carry out the self-monitoring with suitable testing facilities and testing and measuring equipment and maintain the required documentation (see also 6.1.5.1.3, 6.3.5.1.3, 6.6.5.1. 3 ADR / RID or the IMDG Code).

The minimum requirements for packaging testing and test frequencies are listed in Appendix 1.

A.5.5 Notification obligations to BAM

The manufacturer shall inform BAM in advance if

- there will be changes according to A.3.2,
- production is resumed after inactive manufacturing,
- there will be changes to the design type specifications of a dangerous goods packaging.

The manufacturer shall inform the BAM immediately if serious or safety-relevant non-conformities are identified for already delivered dangerous goods packagings.

BAM will decide, after examining the facts and documents submitted, on necessary measures.

A.6 Publication

The status of the recognition of the QAP of the manufacturers will be published on the website of BAM.

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A.7 Costs

Audits and surveillance visits by BAM are due to fees.

Certificates of recognition (first-time recognition, revision and prolongation of recognitions) are due to fees.

The cost of surveillance visits by a surveillance body recognized by BAM shall be contractually regulated between the surveillance body and the manufacturer.

A.8 Requirements for the QAP

Below a suitable structuring of a QAP for the manufacturing of dangerous goods packagings is shown.

Manufacturers often already have a quality management system, such as certification according to ISO 9001 or to another system. For simplification the last column therefore contains cross reference to the respective chapters of ISO 9001:2008.

	Manufacturing and remanufacturing **according to BAM-GGR 001 Part A**	**ISO 9001**
1	**Scope** a) name and address of the manufacturer (manufacturer site), for which the QAP shall apply b) List of the design type codes to be covered by the QAP (e.g. 1A1, 1A2, etc.)	**1**
2	**General requirements for the QAP** a) The QAP shall be documented. b) Manufacturers holding ISO 9001 certification, already, have a QM documentation. This shall be adapted to the requirements in the area of dangerous goods packagings and possibly extended accordingly. c) The QAP shall include the following documents: – table of contents / List of all QSP documents with revision status/ date – documentation on the types approved that are covered by the QAP: at least certificates of design type approval, test reports and further specifications – process, working and testing instructions – information where the current legal bases (eg, ADR / RID, BAM-GGR 001) are available – reference to applicable standards and regulations	**4.1**
3	**preparation, control and revision of QAP documents and records** a) description of how / by whom procedures, working and testing instructions are established, modified and released b) provisions, process, working and testing instructions shall contain the state of revision and date. c) information on retention periods for records (especially test reports), access authorization and data security of documents. d) valid versions of the respective documents, especially work and test instructions, must be available to the personnel.	**4.2**
4	**Responsibility, authority and communication**	
	4.1 Management commitment Statement by which the management of the company (manufacturer) commits himself to comply with the QAP and the legal regulations on dangerous goods.	**5.1**
	4.2 Responsibilities The manufacturer shall specify and communicate the authorities and responsibilities of all employees, especially of those who carry out quality controls and who release processes or products (eg in the form of an organizational chart); especially naming the QAP representative. The QAP representative should report directly to the man-	**5.5** **5.5.1** **5.5.2**

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	agement and should not be bound by instructions.	
5	**Competence and training of the personnel** The manufacturer shall ensure and promote the appropriate qualifications of the personnel, especially the personnel involved in quality control. This includes a) verifiable, appropriate task-related education, skills or experience; b) sufficient, verifiable knowledge of the dangerous goods regulations and standards to be observed (eg, designers must be familiar with ADR Section 6, personnel performing control of incoming goods or packaging testing for final control, must be instructed), c) qualification and training of personnel, d) records of training conducted. Training can be done externally or internally. For oral instructions the contents should be specified; confirmation by signature of the participants is sufficient.	**6.2.2**
6	**Product realisationg**	**7**
	6.1 procedures for new development and changes of specifications a) For each new development of dangerous goods packagings the requirements of the dangerous goods regulations shall be taken into account. To obtain the UN marking, design type testing has to be performed and if necessary a new (revised) type approval must be applied for. For specification changes to an approved design type it must be clarified, whether a revision of the type approval must be applied for and whether a new type examination is necessary. b) If processes are outsourced, these shall be named and regulated, for example, if the application for design type approval is not done by the manufacturer	**7.2.1** **7.3.6** **7.3.7**
	6.2 Purchasing / control of incoming raw materials, closures, etc. It must be ensured that all dangerous goods packagings are made from the materials / components that are specified in the certificate of type approval or in the corresponding design type test report. Control of incoming goods shall be recorded (eg within forms / checklists for comparison of target : actual values). Proof may be, for example, factory test certificates or internal measurements.	**7.4.2** **7.4.3**
	6.3 Manufacturing / re-manufacturing process a) manuals and work instructions for the manufacturing process must be available to the necessary places and must be implemented, especially work instructions for test procedures / frequencies for quality control in the production process (during production, control of the end-product) in accordance with BAM-GGR 001; Checks shall be recorded (forms / checklists for comparison of target : actual values). The batch / lot which was controlled must be identifiable. Results are to be considered and, if necessary, appropriate measures shall be taken. b) If processes are outsourced, these shall be named, regulated and monitored, for example, if individual production steps are carried out externally.	**7.5.1**
	6.4 Marking and traceability Procedures must be available for the a) affixing of the UN marking compliant with the certificate of type approval b) ensuring traceability (from incoming of materials / semifinished products to delivery to the customer) c) records on size of batches per type approval and per design size.	**7.5.3**
	6.5 Preservation of the product Procedures must be available for a) appropriate storage of the finished dangerous goods packagings, b) separation and labeling of released / not released / blocked packagings, c) if applicable, the appropriate transportation to the customer.	**7.5.5**
	6.6 Testing and measuring equipment a) use of suitable equipment, measuring and testing equipment for the respec-	**7.6**

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	tive testing tasks b) measuring equipment must be calibrated: evidence of calibration at specified intervals (eg, calibration, inspection certificates, etc.) c) if possible, information on traceability, method validation, as well as estimates of the measurement uncertainty / accuracy	
7	**Testing, analysis and improvement**	
	7.1 Monitoring and testing of packagings for dangerous goods Ensuring conformity of series production with the approved design type: a) performing the specified packaging testing of finished dangerous goods packagings (final product) b) recording of the performances of the tests and their results. The number of tested samples, batch, design type and the comparison of actual : reference values of the tested samples of dangerous goods packagings shall be identifiable c) evaluation of the test results and, if necessary, taking appropriate measures d) procedures for the release of the finished dangerous goods packagings shall be described e) If testing processes are outsourced, these should be identified, regulated and monitored.	**8.2.4**
	7.2 Control of nonconforming products Process / work instructions for measures according to the type of non-conformity (see A.2.5) to the specifications of the approved design type. Measures might be, for example: a) removal of the UN marking, sorting out b) separate storage of defective products c) if necessary customer information, where required recall of products. Records shall be kept on defective products (which type, which lot / batch, which non-conformity) and on actions taken.	**8.3**
	7.3 Corrective actions a) recording of the corrective actions and review of their effectiveness b) records the cause of the non-conformity and on measures to prevent such non-conformities in the future (eg changes of instructions).	**8.5.2**

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A.9 Attachments and model templates

Attachment 1 Testing and testing frequencies – examples for testing plans

Model template MA.1	audit report
Model template MA.2	surveillance visit report
Model template MA.3	design type specific surveillance protocols
Model template MA.4	report on deviations and non-conformities
Model template MA.5	application for the recognition of the SAP
Model template MA.6	model monitoring contract

Note: The forms and templates (model templates) are provided on the website of BAM. Application is not mandatory, however, it may accelerate the approval / recognition procedure. The contents are minimum requirements and shall be binding.