

Quality Management in Automotive Industry

**Minimum requirements on Management Systems
in AdBlue® production and distribution chain, fol-
lowing the ISO standards 22241, part 1 - 3**

System definition and evaluation

Version 1.5

Copyright protection

This guideline is published under copyright protection. Without approval of VDA every usage outside the tight limits of German copyright protection laws is prohibited and criminal. This is especially imperative in case of copying, translating, microfilming as well as storage and processing in electronic systems.

AdBlue® is a registered trademark of VDA (Verband der Automobilindustrie) and is provided under license from vehicle manufacturers, suppliers and companies of the chemical industry, as well as from the petroleum industry. The brand name AdBlue® is applicable for vehicles, spare parts, in manuals for vehicles and for Urea AUS 32.

If there are any excerpts of ISO standards, they are indicated with the concerned ISO-Number and with allowance of ISO organization. The liability is determined by the currently valid revision of the standard, as indicated by ISO (see also www.iso.org).

2010 All rights reserved Verband der Automobilindustrie e. V. (VDA), Berlin, Germany

Preamble

Urea AUS 32 (Aqueous Urea Solution) is especially developed for automotive SCR converters (Selective Catalytic Reduction). AUS 32 will be injected into the exhaust gas after treatment system to secure a thermally already conditioned and as far as possible homogeneous mixture of AUS 32, his decomposition products and exhaust gas when entering the catalytic converter. By using AUS 32 the catalytic conversion has the optimal effect. Therefore the chemical composition of AUS 32 has to adhere strictly to corresponding ISO standards.

Running of SCR-equipped engines with unsuitable or without AUS 32 will result in a negative impact on the NO_x emission. For that reason sensors are placed in the exhaust pipe to measure the NO_x emission. The measurement results are stored in the OBD-system (On Board Diagnostic) and are periodically controlled.

The consumers of AUS 32 expect high quality standards to prevent any damages at the SCR-systems and to secure a strong reliability of their vehicles, which mostly are in professional use. This demands a close cooperation between the producers of AUS 32 and their customers; e.g. distributors, retailers, haulers, trucking fleets, dispensing organizations and consumers (drivers).

“AdBlue®” is the registered trademark of VDA (Verband der Automobilindustrie) for AUS 32 according ISO 22241. Using the name “AdBlue®” for Urea AUS 32 requires the conformance of the product with ISO 22241 and a license agreement with VDA.

The present guideline has been developed in cooperation between VDA-QMC and some of the concerned AdBlue®-licensees. It is focused on all parties of the AdBlue® industry; including the distribution chain and testing laboratories.

The intention of the guideline is to support those organizations in implementation and continuous improvement of a management system to secure the expected quality standards of AdBlue® in all links of the distribution chain.

Together with corrective actions, recognition of weaknesses in advance and by supervision is the only way to secure the required quality of AdBlue® all over the world. The evaluation of management systems (audit results and certificates) will be accepted by one another inside the AdBlue® industry.

A second intention of the guideline is to enable the customer of each tier level – incl. the final consumers – to recognize the accordance of the product, he intends to buy, with the required quality characteristics. This could happen by labels, certificates and other methods.

Berlin, September 2010

VERBAND DER AUTOMOBILINDUSTRIE E.V (VDA)

Table of content

Preamble	3
1 Introduction	6
1.1 Benefit	6
1.2 Overview	6
1.3 Problem description	7
1.4 Solution	7
1.5 Further development	7
2 Legal aspects	8
3 System definition	9
3.1 Quality characteristics	9
3.2 Production process	9
3.3 Test methods	9
3.4 Quality assurance	9
3.5 Handling, transport and storage	10
4 System evaluation	13
4.1 Auditing	13
4.2 Quality rating system	13
4.3 Evaluation and rating	14
4.4 Scope of the audit	15
4.5 Sampling as part of the audit	19
4.6 Effort for external rating and evaluation	21
4.7 Administrative proceeding	21
4.8 Documentation of audit results	22
4.9 Certificate	22
4.10 AdBlue® label / certificate of conformity	22
5 Requirements and questionnaire	25
5.1 Basic requirements	25
5.1.1 Evidence of a valid license agreement - A	25
5.1.2 Agreement to follow the quality guidelines - A	25
5.1.3 Quality requirements from customers or VDA - A	25
5.1.4 Handling of default documents - A	25
5.1.5 Material safety data sheet (MSDS) - B	25
5.2 Production process	26
5.2.1 Process planning - A	26
5.2.2 Raw material - A	26
5.2.3 Process parameters - A	26
5.2.4 Process flow - A	26
5.2.5 Surrounding conditions - B	26
5.2.6 Handling of non-conforming product - A	26
5.2.7 Problem solving - B	27
5.3 Production equipment	28
5.3.1 Usage of materials compatible with AdBlue® - B	28
5.3.2 Production equipment requirements - B	28
5.3.3 Unintentional contamination of AdBlue® - A	28
5.3.4 Maintenance planning - A	28
5.4 Sampling and testing	29
5.4.1 Written operating procedures for sampling and testing - A	29
5.4.2 Sampling bins - B	29
5.4.3 Samples from filled containers - B	30

5.4.4	Retained samples - B.....	30
5.4.5	Qualification of test laboratories - A	30
5.4.6	Testing - A.....	30
5.4.7	Sampling as part of the audit - A.....	30
5.5	Documentation of test results and certification	31
5.5.1	Evidence of conducted AdBlue® testing - A	31
5.5.2	Existence of certificates of the producers - A.....	31
5.5.3	Minimum content of certificate - B.....	31
5.6	Administration, tracking, batch traceability and labeling	32
5.6.1	Responsibility of the parties - A.....	32
5.6.2	Traceability of containers - A.....	32
5.6.3	Documentation - A	32
5.7	Handling, transport and storage	33
5.7.1	Packaging procedures - A.....	33
5.7.2	Usage of materials compatible with AdBlue® - B.....	33
5.7.3	Equipment requirements - B	33
5.7.4	Handling of containers and equipment - B.....	33
5.7.5	Non-dedicated means of bulk transportation - B.....	34
5.7.6	Minimum contamination test - B.....	34
5.7.7	Unintentional contamination of AdBlue® - A.....	35
5.7.8	Physical conditions during transportation and storage - B	35
5.7.9	Loading or unloading - B.....	35
6	Checklists for auditing	36
6.1	Basic requirements.....	37
6.2	Production process.....	38
6.3	Production equipment.....	39
6.4	Sampling and testing	40
6.5	Documentation of test results and certification	41
6.6	Administration, tracking, batch traceability and labeling	42
6.7	Handling, transport and storage	43
7	Qualification requirements on AdBlue® auditors.....	44
8	Abbreviations and glossary	45
9	Changes.....	46

1 Introduction

The quality of AdBlue® used for the SCR technology needs to be secured to ensure reliable and stable operation of the SCR system.

ISO 22241 series provides specifications for, handling, transportation, storage and refilling interfaces as well as for the test methods, which have to be considered by manufacturers of motor vehicles and diesel engines, by converter manufacturers, by producers and by distributors of AdBlue® as well as by fleet operators.

The series of ISO 22241 standards represents the base for the present guideline.

ISO 22241 is divided in four parts:

ISO 22241 – 1 Quality requirements

ISO 22241 – 2 Test methods

ISO 22241 – 3 Handling, transportation and storing

ISO 22241 – 4 Refilling interface

1.1 Benefit

Precondition for an effective quality management system is the commitment and willing of the Top-Management to implement, support and live the definitions of the management system. The employees have to be committed to the established system as well.

It is necessary that all procedures and processes, with direct or indirect impact on the AdBlue® quality, are well defined and documented. The requirements of the ISO 22241 series have to be considered and their fulfillment has to be checked.

A defined system works, when the definitions are observed. In cases observation of the definitions is not useful in operation; the definitions have to be adapted. A need for readjustment becomes viewable by audits, which have to be conducted on a regular basis – e.g. annual audits internally, triennial audits externally.

As far as the requirements of this guideline are observed, the risk of liability and warranty claims will be reduced; especially with respect to potential license violation and tax evasion.

1.2 Overview

The present guideline includes both, concrete requirements for a quality management system and content with the character of recommendations. Requirements are phrased with “shall”, “must” or “have to”, recommendations with “should” or similar verbs.

In order to make the implementation as easy as possible, there are some checklists included. They can be used as they are or adapted for individual needs. Copyright protection of the guideline does not include the checklists. The checklists might not be exhaustive.

Auditors are supported with detailed requirements and a mandatory evaluation schema. Questionnaires might be useful during the on-site audit.

1.3 Problem description

The AUS 32 solution as specified in the ISO 22241 series is commercially available - among others - under the registered trademark “AdBlue®”.

The owner of this trademark is VDA – Verband der Automobilindustrie e.V., Berlin (Frankfurt), Germany. Licensees of the trademark AdBlue® have committed themselves to comply with the requirements of ISO 22241, part 1, 2 and 3.

There are four cases:

1. Compliant product with license
2. Compliant product without license
3. Not compliant product with license
4. Not compliant product without license

Until yet no independent supervision or observation of the AdBlue® market has been implemented by VDA, as the holder of the trademark, or any other organization.

1.4 Solution

ISO 22241-3 requires purchasing AUS 32 from licensed suppliers only. This has to be verified by documentation, sealed transport units and labeling of transport units and dispensing systems (last ones as far as possible) with an "AdBlue® label", showing the actual batch number of the original producer.

In order to establish an effective quality program, VDA initiates auditing of all links of the distribution chain according the ISO 22241 series and the present guideline. VDA defines the audit requirements (present guideline), conducts the training and the accreditation of the auditors and coordinates the audit activities centrally. Operational auditing and certification of the distribution chain links will be conducted by independent “AdBlue® auditors”. Qualification requirements on AdBlue® auditors are defined in chapter 7 of the present guideline. VDA is in permanent contact with these auditors.

Each audited organization has to pay for auditing and certification by itself. The final consumer (truck driver) is the only one, not being monitored by auditing. But complaints against producers, issued by consumers, will be checked in detail as well.

In case of violation of license requirements VDA will take legal steps to protect the trade mark.

1.5 Further development

VDA intends to publish a list of certified AdBlue® producers and suppliers with a license from VDA and an audited and certified distribution chain on VDA’s website (www.vda.de).

2 Legal aspects

It is not possible for VDA or the licensees of the trademark to decide about changing the ISO standard. This discussion and decision is reserved for ISO and its committees. In case of a change of ISO standards the licensing contracts of VDA demand a direct implementation of further developments of the quality regime for the trademark AdBlue®.

Execution of audits according the present guideline is a mandatory agreement in the AdBlue® license contracts between subscribers and VDA. In case of older contracts, audits happen on a voluntary basis.

Licensees have the responsibility to audit their portion of the distribution chain. The validation of that point is part of the audit process. Auditing of distribution partners of the licensees (e.g. distributor of an AdBlue® producer) is only possible with approval and support of the license partner, since VDA normally has no direct contract with those parties.

Forwarders do not have a license typically (they do not trade), but they adhere to the requirements of ISO 22241 by transportation contract usually. Distributors and trucking fleets are typical links of licensee's distribution chain and will be covered as part of the audit at licensee. He might be asked to provide a random selection of his distributors/trucking fleets to check product at these points during audit.

VDA has no right to gather any samples from distributors, trucking fleets, retailers and truck-owners in principle, because VDA typically has no contract with those parties. Therefore AdBlue®-samples might have to be purchased by VDA.

Several European countries reward a fulfillment of Euro 5 or 6 ahead of time with perquisites like lower road tolls or lower tax rates.

Using the name / trademark "AdBlue®" without direct license agreement with VDA or without a sub-license agreement with a VDA-licensee constitutes a violation of the trade mark.

There is a license violation as well, if licensees produce urea under the name / trademark "AdBlue®" without fulfilling the requirements of ISO 22241-1.

3 System definition

3.1 Quality characteristics

The required quality characteristics of AdBlue® are specified in ISO 22241-1 in detail. They shall be monitored by the manufacturer / producer continuously, following a valid test-plan.

As far as the product fulfills the quality characteristics of ISO 22241-1 producer is allowed to name it “AdBlue®”; precondition is a license agreement with VDA.

3.2 Production process

AdBlue® is produced in 2 different ways:

- Using urea hot- melt from a urea plant and diluting with demineralised water at that location
- Dissolving of solid urea in demineralised water

3.3 Test methods

ISO 22241-2 describes the required test methods for the determination of the quality characteristics of AdBlue®, specified in ISO 22241-1.

The precision of the applied test methods has to be verified by calculating repeatability (r) and reproducibility (R) for each test method.

Sampling of AdBlue® has to be conducted in accordance to ISO 22241-2 and ISO 22241-3; it is valid throughout the distribution chain after shipment from manufacturer's site to the AdBlue® tanks of the vehicles.

3.4 Quality assurance

The fulfillment of the specified quality characteristics has to be ensured throughout the entire distribution chain. Test results shall be noted in writing and shall be kept on file. Sampling instructions defined in ISO 22241-2 and ISO 22241-3 have to be considered.

Each container of AdBlue® brought to the market shall be traceable back to production lot by unique batch numbers. It is recommended to include the date of original manufacturing or the date of last certification. For each production batch of AdBlue® delivered, the manufacturer should supply a quality certificate (e.g. a certificate of compliance with the order or test report).

As e.g. tanks at filling stations are always filled with residues of AdBlue®, using the production batch number of the producer might tamper the traceability rather than guaranteeing it. It pretends that the material coming out of the nozzle is coming from one production batch, only. A unique batch number, defined by any seller in the supply chain based on its own batch history should be preferred in these cases.

All parties of the distribution chain are responsible to supervise their portion of the chain in order to ensure the quality characteristics of AdBlue®.

In case the audited company purchases AdBlue®, it has to be purchased from (other) licensees. Either these licensees have a positive audit result or a clearly defined incoming product inspection must be in place.

Procedures and records concerning production, product delivery, loading, storage, sampling, testing, product release and handling, as well as audits, shall be documented, in accordance with the guidelines of ISO 9001. Quality documents should be kept on file for 5 years.

The quality of AdBlue® taken at any point in the distribution chain shall meet the specifications defined in ISO 22241-1. Sub clauses 5.2 to 5.5 of ISO 22241-3 describe the recommendations related to sampling, testing/checking and monitoring of bulk operations or packaged shipments, as well as the procedures for re-testing and/or re-checking of quality in case of intermediary manipulations (i.e. intermediate tank storing, filling or re-filling).

3.5 Handling, transport and storage

ISO 22241-3 describes best practice recommendations and requirements for handling, transportation and storage of AdBlue®. These recommendations and requirements are necessary to secure the quality characteristics of AdBlue® from the point of production as far as the product is filled into the onboard tank of the vehicle.

In Table 1 of ISO 22241-3 materials are listed, which are compatible with AdBlue®. It is essential to use the correct materials in order to avoid contamination of the product and to resist corrosion of the devices used (containers, tubes, valves, fittings, gaskets, hoses, etc.). It is possible to use other materials than those recommended in table 1 of ISO 22241-3, under the precondition that appropriate tests of compatibility has been conducted, such as ISO 22241-3 paragraph 4.1.1.

In order to avoid any impairment of the AdBlue® quality characteristics prolonged transportation or storage below -5 °C and above 25 °C should be avoided. The product should be protected from sunlight. To avoid contamination during transport and storage either completely closed containers, or containers with air-vents with protective filters should be used. AdBlue® is expected to fulfill the specified quality characteristics for at least the time periods specified in Table 3 of ISO 22241-3.

All surfaces in direct contact with AdBlue® shall be free of foreign matter (fuel, oil, grease, detergent, dust and any other substance). Surfaces of equipment not exclusively used with AdBlue® shall be cleaned before use. The cleaning process should take into consideration the chemical nature of the last three products transported or

stored. Effectiveness of cleaning can be verified by analyzing the quality characteristics of the material used for a last rinsing according to the methods specified in ISO 22241-2.

IBCs (Intermediate Bulk Containers)

IBCs are usually new before first use for AdBlue®. Some producers use reconditioned IBCs, which have been used for other products and are cleaned before use for AdBlue®. IBCs could be used several times for AdBlue® and 1-way as well.

It is not recommended to use reconditioned IBCs. In case they are used, they must be cleaned and checked according to the guidelines for non-dedicated transport equipment.

IBCs are often fitted with a so-called CDS-connection (Coupling Device System) or similar. This is a dry-break connection that enables connection of a pump to take the product from the IBC, without actually opening the IBC. This ensures product quality.

IBCs are sealed after filling. IBCs returned for refill with a broken seal (seal connected to the filling cap is not in place anymore) are obligated for cleaning in accordance to the procedures, as described in ISO 22241 part 3 (point 4.3). In case of any doubt IBC should not be used for AdBlue® anymore.

IBCs are in general filled at the production location of AdBlue® or at a distribution location where professional and dedicated equipment is used to fill IBCs in a clean and controlled environment. More and more suppliers fill IBCs at the location of the customer. Very often just by using the hose to unload the bulk tanker to fill IBCs. This is one of the largest quality risks in the distribution chain and requires reasonable procedures, defined by the producers (licensees), to prevent any risk for AdBlue® quality. It has to be checked during the audit in detail.

Drums

Drums are in general new, used 1-way, or several times with a CDS connector and filled in clean and controlled conditions. Drums are usually sealed after filling.

Cans

Cans are always new, used 1 way and filled in clean and controlled conditions. Cans are sealed after filling. Cans are advised to be sold with a corresponding spout to ensure quality of the product.

AdBlue® is resold and distributed to the transport companies and trucks in different ways. These can be divided into supply to tank stations (Retail) and transport companies and fleet operators (Home Base).

Retail

Tank stations sell the product in cans in the pump shop. The product is available at thousands of tank stations.

Tank stations sell the product “from the nozzle”, like fuel, as well. Product is stored in special equipment and vehicle tanks are filled with special dispensers, approved according to local Weight and Measures regulations.

Product is available from the international fuel companies, smaller local fuel companies, regional small networks owned by local and regional fuel distributors and some individual tank stations.

Home Base

Transport companies and fleet owners are supplied in bulk, IBCs, drums and cans. The supply chain is direct from the AdBlue® producer/supplier or via resellers such as fuel- and lubricants distributors, truck dealers, truck parts dealers, and others.

4 System evaluation

Besides the consideration of guidelines, laws and standards, important facts for the evaluation are managed processes and supervision of the whole distribution chain by independent auditors. Auditors have to be approved by VDA (see chapter 7).

4.1 Auditing

Primary objective of the AdBlue® audits is to validate a full compliance of the audited organization / system with the requirements of ISO 22241, part 1 – 3. To recognize opportunities for optimization in the several procedures is a second aim. Effectiveness of the management system has to be checked and evaluated periodically. The requirements and questions of chapter 5 have to be taken as a basis for this.

The auditor has to take into consideration already existing certifications of the auditee's QM system, e.g. according to ISO 9001. If a valid certificate exists, processes in the company are defined and audited, already. In those cases auditor has to focus on the AdBlue®-specific part of the audit.

Well functioning of the described management system is the basic precondition for a target-oriented and effective fulfillment of the requirements of the present guideline. Rating might be conducted by internal personnel (internal audit), by customer (external second-party audit) or assigned independent auditors (external third-party audit).

Experience taught that it is reasonable to conduct an internal audit prior to an external audit. This is a mean to recognize needs for action in an early stadium. Internal audits should be conducted by qualified personnel only.

4.2 Quality rating system

Within the scope of an audit the process owners have to answer the questions of the present guideline. Implementation and effectiveness of the described processes in operation should be verified by corresponding documents and measurements.

In case of rating a question with “yellow” and evidence of potential or already identifiable risks for the quality of AdBlue®, the auditor has to consider those risks during the evaluation as well.

Rating System

Traffic light symbols	Red	Yellow	Green
Processes described and documented	Not fulfilled	Mostly fulfilled	Fulfilled
Evidence of conformity documented	Not fulfilled	Mostly fulfilled	Fulfilled
Effectiveness in operation	Not verified	Mostly effective	Verified
Risk evaluation	High risk	Medium risk	Low risk

Each requirement in chapter 5 of the present guideline is marked with A or B. These letters work as references to the relevance (weight) of each point in the audit. “A” in-

icates crucial requirements, in sense of critical for the quality of AdBlue®. "A" requirements are weighted with 10. "B" requirements are weighted with 5. Non-fulfillment of "B" requirements does not cause a risk for the quality of the product in any case.

Valuating a requirement with green, means 10 points, with yellow 5 points and with red 0 points. Each valuation will be multiplied with the individual balancing. All multiplications will be summarized and divided by the maximum of accessible points per category; thus each category will have an overall result between 0 and 100.

At the first page of the audit report the overall results of each valuated category will be summarized and divided by the number of valuated categories. The value of this fulfillment rate will vary between 0 and 100 as well. Certificate will be issued, if the fulfillment rate is higher than 80 (%).

In case of rating one "A" requirement with "red", the audit has been failed, independent from the fulfillment rate. Rating of "B" requirements with "red" does not cause the failure of the audit; it influences the fulfillment rate only.

All requirements rated with "red" or "yellow" have to be supported with corrective actions. The audited organization has to provide a corrective action-plan with suitable measures for all requirements / questions rated with "red" or "yellow" within 30 days after the finishing date of the audit.

In case of a failed audit a re-audit has to be conducted within 90 days. Re-audits are limited to auditing the requirements failed in the previous audit. A new audit after a failed re-audit will not be conducted earlier than three calendar months after the date of the re-audit and has to cover the full scope of requirements.

If the audited organization is already an AdBlue® licensee, failed re-audits will not cause the withdrawal of the allowance for AdBlue®-labeling or cancelation of the license. Nevertheless test results out of specification (ISO 22241) can still lead to a withdrawal of the license, according license agreement.

New applicants for an AdBlue® license agreement will not become an official licensee and will not get the allowance for AdBlue®-labeling until an audit according to the present guideline has been concluded with a positive result.

4.3 Evaluation and rating

First step of each audit is to verify whether the requirements of the present guideline have been interpreted, defined, described and documented in the process instructions of the organization (documentation audit).

In a second step the auditor will ask a representative section of the employees if the described procedures are known and implemented (shop-floor audit). The employees might be wanted to supply documents and other evidence for living the described management system in operation. In case the requirements of the present guideline are not completely fulfilled, auditor will evaluate the risk for the quality of AdBlue® in addition.

4.4 Scope of the audit

The audited areas, partners, business units and valuated requirements have to be clarified in advance and documented in the certificate (scope of validity).

Three different parts are characteristic for the production and distribution chain of AdBlue®. Thus it might be helpful to differ between these three parts concerning auditing as well:

1. Production, including bulk storage and bulk loading. This basically covers Ex-works sales of bulk product. No packaging or any kind of transportation involved.
2. Distribution in complete control of licensee (including service providers for storage, transport and packaging directly contracted by the licensee)
3. Distribution (partly or complete in control of others, not owned or directly contracted by licensee)

Scopes 1 and 2 include:

- Bulk transport to storage tanks (owned or directly contracted by the licensee)
- Reloading in bulk from those storage tanks
- Packaging (by licensee or third party directly contracted by licensee)

Scope 3 includes:

- Transport in bulk to reseller, tank station or end-user as far as flange of tank
- Distribution of packages to reseller, storage at reseller
- Distribution of packages to end user

For producers not all locations have to be audited in a first step. That means that 1/3 of all production sites (representing 1/3 of the production volume at least) have to be investigated in the first and the two following audits in principle. The audited locations have to be documented in the certificate, but certificate is valid for the whole organization from the beginning.

Organization and VDA QMC have to take care that all locations will be investigated during three consecutive audits (nine years). The locations, investigated in one audit have to cover 1/3 of the production volume in any case. So it is possible that those locations with the main part of the production volume will be audited every three years. The other audited locations shall be selected randomly, to avoid any decrease of dedication for AdBlue® quality and compliance with the requirements of the ISO standard at the smaller locations. In case of any doubt the triennial audits shall cover rather more than less of 1/3 of all production sites.

For non production licensees the same principle is valid. In this case the term “production sites” includes all sources of supply.

Re-audits have to be conducted at the same locations where the audit has been failed. Additional audits have to be conducted at as many sites (not checked until yet) as the number of sites failed.

Exemplification:

8 locations of 22 have been audited and 2 locations failed the audit requirements

=> Organization failed the audit

=> Re-audit has to be conducted at the 2 locations after implementing corrective actions and at 2 additional locations, which was planned to be audited in three years originally

If re-audit failed again, organization has to apply for a completely new audit at 8 of the 22 locations.

As the complete distribution chain should be part of the audit and the different producers/suppliers have organized their production and supply chain quite different the proposal is to start the audit process with a batch number from product delivered in the market (the batch number either taken from product in the market or from documented batch numbers of the producer) and audit all parts of the distribution chain (including contracted distributors/resellers) from production to end-user. The audited company pays for the complete audit, and thus companies with a complicated supply chain will have more costs for the audit.

The number of batches traced during the audit depends on the size of the audited organization. Auditor has to trace at least one batch per production site during an audit – but 1 batch per 10.000 tons (in rolling 12 months) of production volume / distribution volume per production site. Every time a batch has been divided into different parts, only one specific part has to be traced until it is divided again etc.

For non production licensees the same principle is valid. In this case the term “production sites” includes all sources of supply.

In order to prevent unjustifiable audit-costs the above mentioned “batches per 10.000 tons” have to be traced by investigating the documentation of these batches and the corresponding distribution / delivery papers. Additional on-site inspection has to be conducted for a part of the selected batches during the audit.

The number of batches, which have to be audited by on-site inspection, depends on the summarized production volume / distribution volume of the audited production sites. It is 1 batch per 50.000 tons (in rolling 12 months):

Number of batches, which have to be audited by on-site inspection	Volume in tons (in rolling 12 months)
1	Up to 50.000
2	More than 50.000 up to 100.000
3	More than 100.000 up to 150.000
4	More than 150.000

Exemplification:

An audited organization produces 138.000 tons at 6 production sites

Only 2 of the 6 sites have to be investigated during the audit

Organization produces 53.000 tons at these 2 audited sites

=> Auditor has to trace 2 batches by on-site inspection

=> Auditor should select one batch at each site

An audited organization produces 43.000 tons at 4 production sites

Only 2 of the 4 sites have to be investigated during the audit

Organization produces 19.000 tons at these 2 audited sites

=> Auditor has to trace 1 batch by on-site inspection

=> Auditor should select a batch with the most complicated distribution chain
at 1 of the 2 audited sites

Following table shows the requirements of the present guideline to be audited at the several types of organizations:

	relevance (weight)	New producer (licensee)	Producer (licensee)	Distribution chain, Logistics	Trader
5.1 Basic requirements					
5.1.1 Evidence of a valid license agreement	A		X		X
5.1.2 Agreement to follow quality guidelines	A	X	X	X	X
5.1.3 Quality req. from customers or VDA	A	X	X	X	X
5.1.4 Handling of default documents	A	X	X	X	X
5.1.5 Material safety data sheet (MSDS)	B	X	X	X	X
5.2 Production process					
5.2.1 Process planning	A	X	X		
5.2.2 Raw material	A	X	X		
5.2.3 Process parameters	A	X	X		
5.2.4 Process flow	A	X	X		
5.2.5 Surrounding conditions	B	X	X		
5.2.6 Handling of non-conforming product	A	X	X		
5.2.7 Problem solving	B	X	X		
5.3 Production equipment					
5.3.1 Usage of materials comp. with AdBlue®	B	X	X		
5.3.2 Production equipment requirements	B	X	X		
5.3.3 Unintentional contamination of AdBlue®	A	X	X		
5.3.4 Maintenance planning	A	X	X		
5.4 Sampling and testing					
5.4.1 Written procedures for sampl. & test.	A	X	X	X	
5.4.2 Sampling bins	B	X	X	X	
5.4.3 Samples from filled containers	B	X	X	X	
5.4.4 Retained samples	B	X	X	X	
5.4.5 Qualification of test laboratories	A	X	X	X	
5.4.6 Testing	A	X	X	X	
5.4.7 Cross-check of retained samples	A		X	X	
5.5 Doc. of test results and certification					
5.5.1 Evidence of conducted AdBlue®-testing	A	X	X		
5.5.2 Existence of certificates of producers	A	X	X		
5.5.3 Minimum content of certificate	B	X	X		
5.6 Administration, tracking, batch traceability and labeling					
5.6.1 Responsibility of the parties	A	X	X	X	
5.6.2 Traceability of containers	A	X	X	X	
5.6.3 Documentation	A	X	X	X	
5.7 Handling, transport and storage					
5.7.1 Packaging procedures	A	X	X	X	X
5.7.2 Usage of materials comp. with AdBlue®	B	X	X	X	X
5.7.3 Equipment requirements	B	X	X	X	X
5.7.4 Handling of containers and equipment	B	X	X	X	X
5.7.5 Non-dedicated means of bulk transp.	B	X	X	X	
5.7.6 Minimum contamination test	B	X	X	X	
5.7.7 Unintentional contamination of AdBlue®	A	X	X	X	X
5.7.8 Physic. cond. during transp. & storage	B	X	X	X	X
5.7.9 Loading or unloading	B	X	X	X	X

4.5 Sampling as part of the audit

Production of AdBlue®

Producers of AdBlue®, which have implemented a Quality Management System according to DIN EN ISO 9000 series (or other accepted Quality Management standards), should conduct product tests in compliance with ISO 22241-2 periodically. The internal test laboratory and the test procedures can be evaluated and rated separately or during an overall audit of the organization on the basis of the present guideline.

Producers without a certified Quality Management System have to conduct those tests at certified and accredited test laboratories or other adequate qualified third-party experts.

In both cases fulfilling of the requirements of ISO 22241-1 has to be documented for each lot and batch of AdBlue® production.

Auditor has to initiate crosschecks (control tests) of retained production samples during the audit by a certified and accredited test laboratory. The re-assessed samples have to be selected at random out of production or retained production samples – but not out of the distribution chain. The number of such crosschecks depends on the size of the audited organization and is defined in the following table:

Number of samples	Production volume in tons (in rolling 12 months)
2	Up to 50.000
3	Up to 150.000
4	More than 150.000

Samples from a specific organization should be from different batches. In case of any doubt, a higher number of samples should be checked.

Criteria for the evaluation of the samples are significant non-compliance between the test results (reproducibility according to ISO 22241, part 2) and negative test results (out of specification according to ISO 22241, part 1).

It is assumed that all retained samples meet the requirements of the specification. Batches, which do not fulfill the requirements, are not allowed to be distributed as AdBlue®. So it should be rather unlikely for an auditor to find retained AdBlue® production samples, which are out of specification.

Aim of the crosschecking during the audit is to validate the implemented internal supervision procedures of the audited organization. Crosschecking during the audit is not a substitution for the required internal supervision. Independent from auditing, any AdBlue® production, which does not meet the requirements of ISO 22241-1, is not tolerated. In case a retained sample is found to be out of specification, when crosschecked, will cause a failure of the audit, since requirement 5.4.7 in chapter 5 has to be rated with “red”.

Packaging, Distribution and Reselling of AdBlue®

When AdBlue is stored, transported and/or packed, samples should be retained as well. ISO 22241 clearly identifies which samples from the various stages of the process and the different batches must be retained. As part of the audit, the auditor has to take samples from delivered product to have the quality verified.

Auditor has to initiate crosschecks (control tests) of retained samples of the packaging process during the audit by a certified and accredited test laboratory. In case the audited organization has not retained samples, auditor will select the samples for crosschecking out of the currently available storage at random. The number of samples, which have to be checked during the audit depends on the distribution volume of AdBlue® and is defined in the following table:

Number of samples	Distribution volume in tons (in rolling 12 months)
4	Up to 50.000
6	Up to 150.000
8	More than 150.000

Samples from a specific organization should be from different batches. In case of any doubt, a higher number of samples should be checked.

In case of significant non-compliance (reproducibility according ISO 22241, part 2) between the test results or negative test results (out of specification according ISO 22241, part 1) two additional samples have to be taken as a contra-expertise and they need to be correct. All samples should be tested by the same laboratory.

At maximum 20% of the samples from the market are allowed to be out of specification (quality characteristics or reproducibility). Exceeding of the maximum allowable failure rate of 20% will cause a failure of the audit, since requirement 5.4.7 in chapter 5 has to be rated with "red".

Exemplification:

4 samples are taken and 1 is out of specification

=> Organization failed the quality check (1 failure, resp. 25% failure rate)

=> 2 additional samples have to be taken and both meet the specification

=> OK (1 failure but 17% failure rate only)

4 samples are taken and 1 shows a significant non-compliance to the primary test result

=> Organization failed the quality check (1 failure, resp. 25% failure rate)

=> 2 additional samples have to be taken and another one is out of specification

=> Organization failed the quality check (2 failures, resp. 33% failure rate and one of the additional samples is out of specification, which is not allowed)

8 samples are taken and 1 is out of specification.

=> OK (1 failure but 13% failure rate only)

Consistent exceeding of the maximum allowed failure rate may cause the withdrawal of the allowance for AdBlue®-labeling and cancelation of the license. The producer of the product should get a chance to comment before VDA conducts further steps.

The costs for crosschecking of the product have to be paid by the audited organization (licensee or sub-licensee) in principle.

4.6 Effort for external rating and evaluation

External audits at foreign organizations have to be conducted by qualified and independent auditors.

Effort of the external evaluation of the management system has to be inside the tight limits of cost-effectiveness. An audit should be conducted within 8 hours per site, depending on the size of the audited organization, in particular if the auditee holds a valid QM system certificate. In case of additional evaluation of included test-laboratories or links of the distribution chain the default might be higher.

Principle steps during the audit:

- Inspection of the management system documentation
- Inspection of the process instructions
- Observations and Interviews on shop floor
- Internal discussion between the auditors and evaluation
- Creation of audit report
- Presentation of audit results
- Definition of corrective actions; as far as necessary

The audited organization has to finance the audit completely; in example labor time, travelling costs and expenses for overnight accommodation of the auditor.

4.7 Administrative proceeding

The responsible person of an organization, which intends to conduct an AdBlue® audit, has to contact VDA QMC. Current responsibilities inside VDA QMC can be checked at QMC's homepage (www.vda-qmc.de).

The representative of the company and QMC will agree upon the scope, the location and the time frame of the audit. Afterwards QMC will determine the auditor and share the contact data between auditor and the responsible contact person of the company.

Scheduling and definition of further details of the audit will be clarified between the auditor and the responsible contact person of the company directly.

After conclusion of the audit QMC will issue the certificate, update the data base and conduct the financial settlement.

4.8 Documentation of audit results

Audit results are useful to make recognizable the remaining potentials for optimization and improvement of the audited organization. Any deviation from expected results (requirements) will be listed as a part of the audit report.

The audit report will be subscribed by the auditor and by the responsible person of the audited organization. Subscription by the person, responsible for the overall AdBlue® business (or maybe one level upwards in the organization), confirms that the documented audit results has been discussed and explained, as far as necessary.

All information cumulated by the auditors during the audit has to be handled strictly confidential, apart from the result of the audit itself.

4.9 Certificate

Aim of the certificate is to create confidence on both sides of the business partners. A system certificate demonstrates that an audit in accordance with the present guideline has been conducted. It provides the evidence that the implemented management system is in compliance with the requirements of ISO 22241 series.

The main elements of the audit result are the auditor's report and the recommendation concerning issuing of the certificate. On the basis of these two facts VDA will issue the certificate, as far as auditor's evaluation of the situation found and his recommendation concerning the certification will be approved by VDA. Issuing of the certificate causes additional costs, which will be debited to the audited organization.

The certificate has a validation time of three years, starting at the date of issuing. List of audited areas, partners, business units and valuated requirements will be documented in the certificate (scope of validity).

4.10 AdBlue® label / certificate of conformity

An AdBlue® label symbolizes the conformance of a product with the required quality characteristics of AdBlue®, specified in ISO 22241-1. Primary goal of labeling the AdBlue® packages is to ensure that the conformance of the product with ISO 22241 series is easily recognizable by customers and consumers in each link of the distribution chain.

Beside the trademark "AdBlue®" label has to declare the place of production, the original production lot of the substance and the production date as well. In addition to a label, AdBlue® seals can also be used.

The label has to be displayed clearly on front of IBC (Intermediate Bulk Container), drum, can, bulk road tanker or dispenser. Minimum size of the label is 10 x 5 centimeters. Translation in English around outside of label is encouraged.

The label has to display at a minimum:

- Trademark “AdBlue®” (might be outside the label)
- Name of the substance (commercial name, trademark; option: generic name)
- Producer: name, address, phone (option: hotline for consumers)
- No. and date of batch

For bulk road tanker there is no need to declare bullet points 1, 3, 4, as this information is always given in the shipping documents on the truck, which have to be kept on file anyway for other reasons.

Design specifications concerning lay-out of label or seal are not defined. Usage of the noun “AdBlue®” itself has to be part of an AdBlue® trademark license agreement already. Other already existing legal requirements concerning labeling have to be observed as well.

Remarks for the auditor

Labeling of all transport units with an AdBlue® label might be difficult since some of the transport units are non-dedicated. But all transport units should have a numbered seal on all loading and unloading connections or openings. The number of the seal must be mentioned on the transport documents. However when units are used for so-called milk routes (where various smaller tanks on different locations are filled from one transport unit) these seals are only intact until first delivery. For smooth unloading the cover of the loading opening will be opened a little to allow air to enter the transport unit. Sealing would be useless in these cases.

On the other hand dedicated transport units like trailers, tank containers or railcars are returning from unloading locations to loading locations on rail or ferry without being accompanied by people. To ensure clean arrival at the loading point these transport units should be sealed before returning. The same is valid for transport units (full or empty) that are parked (over night or for other reasons) without being accompanied by people.

The responsibility for traceability of batch number of the original product goes only as far as the product has been reloaded into a bulk tank on customer site. Tanks will be refilled before they're empty and thus batches would always be mixed in a bulk tank (filling station or fleet owner).

In order to secure a minimum level of confidence from supplier to customer in case of bulk delivery, each delivery of AdBlue® has to be accompanied with an individual certificate of conformity. Those certificates have to document the over-all compliance of the delivered product with the required quality characteristics of AdBlue®, specified in ISO 22241-1.

Required information as part of the certificate of conformity:

- Part A - Company information
(name, address and contact information)
- Part B - Product data
(type and description of tested product, physical and chemical properties, lab test data and pre-supplier information if necessary, reference to ISO 22241-2 (=> test methods as given in ISO 22241-1), precision of the test method (repeatability and reproducibility), deviations from the specified mode of operation, if any)
- Part C – Traceability
(e.g. sampling method used, batch number, production date, test date, bottling location and brand identifier)

Checking the completeness of documentation will be part of an audit according the present guideline.

In case of packed product delivery individual certification for each item would create an unjustifiable amount of work (and cost). The above mentioned usage of an AdBlue® quality label in combination with information concerning traceability should be sufficient to assure the required quality of AdBlue® concerning this kind of packaging.

In this respect information on the packed material concerning the bottling (packaging) location is the best way to tackle potential quality issues related to filling IBCs in more or less uncontrolled circumstances (or in other words: direct from a bulk road vehicle into the IBCs at customer's site).

5 Requirements and questionnaire

Categories:

A = “crucial” – weighted with factor 10

B = “should have” – weighted with factor 5

5.1 Basic requirements

5.1.1 Evidence of a valid license agreement - A

- Is there a valid license agreement with VDA or any kind of sub-license agreement with a VDA-licensee?

5.1.2 Agreement to follow the quality guidelines - A

- Has each party involved in the supply or distribution chain signed an agreement that they will follow the quality guidelines, including traceability of the product as mentioned in ISO 22241?

5.1.3 Quality requirements from customers or VDA - A

- Are all necessary quality requirements from customers or VDA available, valid and understood?

5.1.4 Handling of default documents - A

- Are responsibilities for identification, revision and approval of default documents defined?
- Is a reliable change management in place?
- Is defined, how long which kind of documents have to be archived?
- Is ensured that invalid documents cannot be in use on shop floor?

5.1.5 Material safety data sheet (MSDS) - B

- Is a specific MSDS available for the product and shared to the persons handling AdBlue®?
- Does MSDS contain indications on the hazard ranking and other regulations to be respected?
- Does MSDS contain measures required to be taken for the protection of persons and of the environment when handling the product?

5.2 Production process

5.2.1 Process planning - A

- Have production processes been planned?
- Are there sufficient work instructions in place and are they understood by personnel?

5.2.2 Raw material - A

- Is ensured, that raw material meets the required specifications?
- Is an incoming inspection in place?
- Are the results of incoming inspection documented?
- Have corrective actions been taken and documented in case of nonconformance?

5.2.3 Process parameters - A

- Are process parameters monitored and documented?
- Are there corrective actions in place in case of process parameters do not meet the allowed tolerances?
- Has been documented what kind of corrective actions have been conducted when and by whom?

5.2.4 Process flow - A

- Is ensured that only those intermediates go to the next production step which met the individual quality requirements?

5.2.5 Surrounding conditions - B

- Are all necessary conditions of the production environment defined (e.g. temperature, humidity, cleanliness and storage conditions)?
- Are those requirements known by personnel and adhered?

5.2.6 Handling of non-conforming product - A

- Is ensured that in case of deviation of any process parameter from specification the product has been withheld, stored separately and labeled accordingly?
- Is ensured that in case of any other doubt about the quality of the product (e.g. containers without labels, colored or cloudy product, uncharacteristic smell or exceeded shelf life) product has been withheld, stored separately and labeled accordingly?
- Is ensured that suspect products re-enter the distribution chain only when product quality has been checked again and verified that the quality standards defined in ISO 22241-1 are fulfilled?
- Are adequate procedures defined and implemented to ensure that concerned shipments will be recalled, if the results of an analysis reveal that AdBlue® from the same production batch has the same fault?
- Has product that has been recalled in this way and judged not to be in compliance with the specification been downgraded and is ensured that such product will no longer be designated as AdBlue®?

5.2.7 Problem solving - B

- Have further investigations been carried out in case of emergence of non-conforming product?
- Do customer complaints and feedback from end customers (consumers) come into consideration concerning problem solving as well?
- Have actions been conducted to prevent recurrence of the same failure?
- Have taken corrective actions been documented?
- Is the actual Quality level of AdBlue® production and distribution chain known and reported to Top-Management on a regular basis?

5.3 Production equipment

5.3.1 Usage of materials compatible with AdBlue® - B

- Are all materials in direct contact with AdBlue® during production compatible with AdBlue® (see Table 1 of ISO 22241-3 — Examples of recommended materials)?
- Have appropriate tests of compatibility been conducted such as ISO 22241-3 paragraph 4.1.1, in case other materials than those recommended in table 1 of ISO 22241-3 are in use?

5.3.2 Production equipment requirements - B

- Are all surfaces in direct contact with AdBlue® free of foreign matter (fuel, oil, grease, detergent, dust or any other substance)?
- Have all surfaces of equipment, not exclusively used with AdBlue®, been cleaned with distilled or de-ionized water and AdBlue® in the last cleaning step immediately before the use with AdBlue®?
- Is verified that the trace elements specified in ISO 22241-1, Table 1, in the AdBlue® that is used for a last rinsing are within the specification using the methods specified in ISO 22241-2?
- Has the result of cleaning for storing and transportation facilities been verified by analyzing the AdBlue® used for a last rinsing according to the methods specified in ISO 22241-2?
- Has the cleaning been documented (e.g. certificate of cleanness)?
- Have corrective actions been taken and documented in case of nonconformance?

5.3.3 Unintentional contamination of AdBlue® - A

- Are there investigations carried out to determine the causes of a contamination in cases a contamination of AdBlue® is detected during production?
- Have appropriate corrective actions taken place?
- Have actions been conducted to prevent recurrence of the same failure?
- Have taken corrective actions been documented?

5.3.4 Maintenance planning - A

- Is verification and calibration of production- and testing-equipment planned and have responsibilities been defined?
- Are there sufficient verification- and calibration-instructions in place and are they understood by personnel?
- Has conducting of verification and calibration been documented?
- Are due dates for the next verification and calibration of production- and testing-equipment defined and are these due dates known by / recognizable for personnel (e.g. by batches)?

5.4 Sampling and testing

5.4.1 Written operating procedures for sampling and testing - A

- Are written operation instructions for sampling and testing available?
- Have details of the sampling procedures been adapted to the purpose of AdBlue® sampling (see ISO 22241-3 for examples)?
- Are standard operation procedures installed to ensure that samples are representative for the tested lot?
- Do operation instructions content the requirement that first filling of the sampling bin shall be discarded, and that bottle shall immediately be re-filled with specimen (AdBlue®) and closed tightly in a second step?

5.4.2 Sampling bins - B

- Check audit results of ISO-certification – if exist. As far as those have been valuated as OK, this audit score can be rated with “green” as well.
- Are suitable bins (e.g. bottles) in use for sampling, which do not contaminate the sample, especially regarding the trace elements, and do they minimize the risk of algae or bacteria growth?
- Is ensured that the sampling bins are protected against the following sources of contamination, which would imply a major hazard:
 - Residues of process aids used for the production of the sampling bottles
 - Contaminants which have been deposited in the empty bottles during the time they are stored empty
 - Contaminants from the air, i.e. dust or any foreign matter from the surrounding, during the sampling
 - Residues of cleaning agents, which have been used for cleaning the sampling equipment and the bottles as well
 - Fuel
- Are these bottles made of HD-polyethylene, HD-polypropylene, polyfluorethylene, polyvinylidenedifluoride and tetrafluoroethylene-perfluoroalkyl vinyl ether copolymer (PFA)?
- Have the bottles been cleaned and finally rinsed with de-ionized water followed by AdBlue®, prior to the first use with AdBlue®?
- Have corrective actions been taken and documented in case of nonconformance?
- Is each bottle labeled by using labels of approximately 10 cm × 5 cm?
- Is label attached to the bottle loss-proofed?
- Are labels and writing on these labels resistant to water and AdBlue®?
- Does the label provide the following information:
 - Name of the substance (commercial name, trademark; option: generic name)
 - Producer name (option: address, phone, hotline for consumers)
 - No. and date of batch

5.4.3 Samples from filled containers - B

- Has a sample been taken from the filled container after loading of any means of bulk transportation at the production site?

5.4.4 Retained samples - B

- Have enough samples been taken in the distribution chain when handling bulk AdBlue® (recommendation: 1 liter)?
- Is ensured that during filling of a series of small containers with AdBlue®, a one liter sample has been taken from the first container filled?
- Is ensured that the sample taken will be the first filled container, if the containers are smaller than one liter in size? The sample should be kept as a retention sample.
- Have samples kept safe for at least the shelf life of the volume of AdBlue® (recommendation: minimum 12 months)?
- Does storage of retained samples happen under appropriate physical conditions (see chapter 5.7)?

5.4.5 Qualification of test laboratories - A

- Does internal test laboratory provide sufficient qualification, either by:
 - laboratory that has a quality management system, e.g. in accordance with ISO 9001
 - laboratory that has successfully taken part in internationally organized round-robin tests of AdBlue® within the preceding five years
 - laboratory certified by national authorities
- Is ensured that testing has been conducted by certified and accredited test laboratories or other adequate qualified third-party experts in case of uncertified producers (insufficient qualification of the internal test laboratory)?

5.4.6 Testing - A

- Has testing been conducted in accordance with ISO 22241-2?
- Have the testing results been documented?
- Have corrective actions been taken and documented in case of nonconformance?
- Has the analysis been conducted within three weeks after sampling in order to prevent possible changes in the ammonia content?

5.4.7 Sampling as part of the audit - A

- Auditor chooses at least two samples and initiates a cross-check of the samples by a certified and accredited test laboratory. Does test result comply with the documented results conducted by the audited organization? (consider chapter 4.5 of the present guideline)

5.5 Documentation of test results and certification

5.5.1 Evidence of conducted AdBlue® testing - A

- Is there any kind of manufacturing process verification in place?
- Has each production batch of AdBlue® been tested prior to shipment, in order to verify the accordance of the product with the specifications, defined in ISO 22241-1?

5.5.2 Existence of certificates of the producers - A

- Are the results of incoming inspection documented and traceable to the delivered and produced batches?
- For each production batch of AdBlue® delivered, the producer should supply a quality certificate (e.g. a certificate of compliance with the order or test report). Are those certificates available and stored for each produced, supplied or delivered batch of AdBlue®?
- Are certificates stored for at least 24 months?

5.5.3 Minimum content of certificate - B

- Does the certificate include the following data as a minimum requirement:
 - Part A - Company information
(name, address and contact information)
 - Part B - Product data
(type and description of tested product, physical and chemical properties, lab test data and pre-supplier information if necessary, reference to ISO 22241-2 (= test methods as given in ISO 22241-1), precision of the test method (repeatability and reproducibility), deviations from the specified mode of operation, if any)
 - Part C – Traceability
(e.g. sampling method used, batch number, production date, test date, bottling location and brand identifier)

5.6 Administration, tracking, batch traceability and labeling

5.6.1 Responsibility of the parties - A

- All parties of the distribution chain have the responsibility to audit their portion of the chain so as to ensure the quality of AdBlue®. Have sufficient actions been taken by the responsible parties to resolve any identification problems occurred?
- Have licensee specific procedures in place to prevent potential Quality loss at high risk points of the distribution chain, like filling IBCs in uncontrolled or less controlled circumstances?
- Does purchased urea fulfill the requirements of ISO 22241, in case of auditing a distributor?

5.6.2 Traceability of containers - A

- Each container of AdBlue® brought to the market has to be traceable back to production batches of AdBlue® by way of a unique batch number. Does each container have an identification seal, label or stamp, so that its content can be traced back to the original production batch?
- Are filled containers sealed, unless the container has a vented design?
- Is it possible to track the route trip of road tankers, vessels or rail wagons in case of distributing AdBlue® as bulk material (loading location, transshipping stations (if any) and unloading location)?

5.6.3 Documentation - A

- Have all records of the distribution chain of AdBlue® concerning production, product delivery, loading, storage, sampling, testing, product release and handling, as well as audits, been documented, in accordance with the guidelines of ISO 9001 or other adequate Quality standards?
- Have Quality documents been kept on file for 5 years or at least as long as defined in corresponding internal procedures or operation instructions?

5.7 Handling, transport and storage

5.7.1 Packaging procedures - A

- Are all bulk loading and unloading operations established as operation instructions?
- Have packaging procedures been defined?
- Do these operation instructions include requirements concerning the specific physical conditions during transportation and storage of AdBlue®?
- Are operation instructions in place and understood by personnel?
- Do checklists exist to document loading and unloading steps?
- Are these checklists signed by a person responsible for the loading or unloading procedure and by the operator in charge of transportation?
- Are these checklists retained by the department or organization responsible for loading or unloading?
- Are these checklists available for random check during the audit?

5.7.2 Usage of materials compatible with AdBlue® - B

- Are all materials in direct contact with AdBlue® during handling, transportation and storing, including sampling compatible with AdBlue® (see Table 1 of ISO 22241-3 — Examples of recommended materials)?
- Have appropriate tests of compatibility been conducted such as ISO 22241-3 paragraph 4.1.1, in case other materials than those recommended in table 1 of ISO 22241-3 are in use?

5.7.3 Equipment requirements - B

- Are all surfaces in direct contact with AdBlue® free of foreign matter (fuel, oil, grease, detergent, dust or any other substance)?
- Have all surfaces of equipment, not exclusively used with AdBlue®, be cleaned with distilled or de-ionized water and AdBlue® in the last cleaning step immediately before the use with AdBlue®?
- In cases distilled water or de-ionized water is not readily available and material has been cleaned with tap water, is ensured that the last rinse is done using the AdBlue® to be handled with the equipment?
- Is verified that the trace elements specified in ISO 22241-1, Table 1, in the AdBlue® that is used for a last rinsing are within the specification using the methods specified in ISO 22241-2?
- Has the result of cleaning for storing and transportation facilities been verified by analyzing the AdBlue® used for a last rinsing according to the methods specified in ISO 22241-2?
- Have cleaning results been documented (e.g. certificate of cleanness)?
- Have corrective actions been taken and documented in case of nonconformance?

5.7.4 Handling of containers and equipment - B

- Is the equipment dedicated for use with AdBlue® identified accordingly?
- Is a rinsing certificate presented by the forwarder to the producer at first loading, in case of dedicated transportation means?

- Have all components of the filling and emptying equipment been emptied, cleaned and closed off after use, in order to prevent contamination of AdBlue® from the surroundings?
- Have hoses, in particular, been dedicated and closed after every use, and handled and stored in a controlled manner?
- Are closing and proper handling confirmed by a visual inspection at the filling station and documented accordingly?
- Have all containers been checked visually prior to filling to recognize foreign matter such as dust, insects or any other insoluble matter?
- Does checking happen in accordance with a written procedure or does a checklist exist?
- Is ensured that in case of finding any discrepancy to the above mentioned requirements, an adequate problem solving process starts?

5.7.5 Non-dedicated means of bulk transportation - B

- Have the outlet, the inlet and the interior of the means of transportation and storing been cleaned, in case non-dedicated means have been used for bulk transportation of AdBlue®?
- Are the last three products transported or stored in those non-dedicated means documented?
- Does the cleaning process take into consideration the chemical nature of the last three products transported or stored in those non-dedicated means of bulk transportation or storing?
- Are the cleaning process and the cleanness itself documented in an appropriate certificate of cleanness? This certificate should be presented at the site of filling prior to loading.
- Have the outlet, the inlet and the interior of the means of transportation and storing been checked visually?
- Is ensured that container will not be filled and rejected, if the visual check reveals noncompliance with the cleanness requirements? Additional cleaning or replacement has to be performed and must be verifiable.
- Has an analysis been conducted before delivery of AdBlue®, if non-dedicated means of bulk transportation have been used?
- Have corrective actions been taken and documented in case of nonconformance?

5.7.6 Minimum contamination test - B

- Does a minimum contamination test consist of checking the product for color, suspended particles and odor different from ammonia?
- Have such minimum contamination tests been performed every time the product in bulk is transferred from one bulk container to another bulk container?
- Have the testing results been documented?
- Have corrective actions been taken and documented in case of nonconformance?

5.7.7 Unintentional contamination of AdBlue® - A

- Are there investigations carried out to determine the causes of a contamination in cases a contamination of AdBlue® is detected during handling, transportation and storing?
- Have appropriate corrective actions taken place?
- Have actions been conducted to prevent recurrence of the same failure?
- Have taken corrective actions been documented?

5.7.8 Physical conditions during transportation and storage - B


- Are insulations or means of heating the AdBlue® installed for transportation vehicles, if necessary?
- Has AdBlue® been protected from sunlight throughout storage and delivery in order to avoid an excessive temperature rise of the product?
- Is ensured that only well-closed containers or vented containers with filters are in use to protect AdBlue® from any contamination carried by air?
- As a function of the constant ambient temperature at which AdBlue® is stored, product is expected to remain within the specifications given in ISO 22241-1 for the time periods specified in Table 3 of ISO 22241-3 at least. Has every batch, whose shelf life has expired, been checked in this manner before use?
- Have corrective actions been taken and documented in case of nonconformance?

5.7.9 Loading or unloading - B

- Are the results of the following inspections documented prior to any loading or unloading of AdBlue® as a minimum:
 - Proper closure of all valves and apertures after completion of the loading or unloading procedure;
 - Check of the certificate of cleanness (for the first filling of a dedicated bulk container with AdBlue®);
 - Visual verification of the means of bulk transportation or storage, the loading and unloading equipment, the ancillary equipment and the systems for cleanness, defects or faults;
 - Identification of products to be loaded or unloaded in accordance with the delivery documents.
- Is ensured that operation will be stopped immediately, if any irregularities occur during loading or unloading?
- Have samples from filled bulk compartments been analyzed to clarify occurred irregularities during loading or unloading?
- Are investigations carried out to determine the causes of irregularities?
- Have appropriate corrective actions taken place?
- Have actions been conducted to prevent recurrence of the same failure?
- Have taken corrective actions been documented?

6 Checklists for auditing

AdBlue - Certification Audit



Qualitäts Management Center
im Verband der Automobilindustrie

Report no. of the Audit _____

Audit Start date _____

Audit End date _____

Certification party _____

Department / Organization AdBlue-Auditing

Auditor / Name _____

Audited / certified party _____

Department / Organization _____

Responsible person / Name _____

Address / Street _____

City / ZIP code _____

Country / State _____

Audited locations _____

Audited units _____

	Valuated requirements	No. of red A req.	No. of red B req.	No. of yellow	No. of green
5.1 Basic requirements	0	0	0	0	0
5.2 Production process	0	0	0	0	0
5.3 Production equipment	0	0	0	0	0
5.4 Sampling and testing	0	0	0	0	0
5.5 Documentation of test results and certification	0	0	0	0	0
5.6 Administration, tracking, batch traceability and labeling	0	0	0	0	0
5.7 Handling, transport and storage	0	0	0	0	0
Total (max. 38):	0	0	0	0	0

Overall Result Fulfillment rate [%]:

Issuing of certificate recommended Yes No

Remarks: _____

Signature audited party

Signature Auditor

ok

nok

No. of certificate	Date of issuing	Result of cross-check	Signature VDA
--------------------	-----------------	-----------------------	---------------

6.1 Basic requirements

AdBlue - Certification Audit		Audited organization:				
5.1 Basic requirements		Date of visit:			to	
Evaluation r/y/g/n.v.	Question No.	Observation	Measures	Responsibility	Date	Status [%]
	5.1.1	Evidence of a valid license agreement directly with VDA or in form of a sub-license				
	5.1.2	Agreement to follow the quality guidelines				
	5.1.3	Quality requirements from customers or VDA				
	5.1.4	Handling of default documents				
	5.1.5	Material safety data sheet (MSDS)				

6.2 Production process

AdBlue - Certification Audit		Audited organization:				
5.2 Production process		Date of visit:			to	
Evaluation r/y/g/n.v.	Question No.	Observation	Measures	Responsibility	Date	Status [%]
	5.2.1	Process planning				
	5.2.2	Raw material				
	5.2.3	Process parameters				
	5.2.4	Process flow				
	5.2.5	Surrounding conditions				
	5.2.6	Handling of non-conforming product				
	5.2.7	Problem solving				

6.3 Production equipment

AdBlue - Certification Audit		Audited organization:				
5.3 Production equipment		Date of visit:			to	
Evaluation r/y/g/n.v.	Question No.	Observation	Measures	Responsibility	Date	Status [%]
	5.3.1	Usage of materials compatible with AUS 32				
	5.3.2	Production equipment requirements				
	5.3.3	Unintentional contamination of AdBlue				
	5.3.4	Maintenance planning				

6.4 Sampling and testing

AdBlue - Certification Audit			Audited organization:			
5.4 Sampling and testing			Date of visit:		to	
Evaluation r/y/g/n.v.	Question No.	Observation	Measures	Responsibility	Date	Status [%]
	5.4.1	Written operating procedures for sampling and testing				
	5.4.2	Sampling bins				
	5.4.3	Samples from filled containers				
	5.4.4	Retained samples				
	5.4.5	Qualification of test laboratories				
	5.4.6	Testing				
	5.4.7	Sampling as part of the audit				

6.5 Documentation of test results and certification

AdBlue - Certification Audit		Audited organization:				
	5.5 Documentation of test results and certification	Date of visit:		to		
Evaluation r/y/g/n.v.	Question No.	Observation	Measures	Responsibility	Date	Status [%]
	5.5.1	Evidence of conducted AdBlue testing				
	5.5.2	Existence of certificates of the producers				
	5.5.3	Minimum content of certificate				

6.6 Administration, tracking, batch traceability and labeling

AdBlue - Certification Audit		Audited organization:				
5.6 Administration, tracking, batch traceability and labeling		Date of visit:			to	
Evaluation r/y/g/n.v.	Question No.	Observation	Measures	Responsibility	Date	Status [%]
	5.6.1	Responsibility of the parties				
	5.6.2	Traceability of containers				
	5.6.3	Documentation				

6.7 Handling, transport and storage

AdBlue - Certification Audit			Audited organization:			
		5.7 Handling, transport and storage	Date of visit:		to	
Evaluation r/y/g/n.v.	Question No.	Observation	Measures	Responsibility	Date	Status [%]
	5.7.1	Packaging procedures				
	5.7.2	Usage of materials compatible with AUS 32				
	5.7.3	Equipment requirements				
	5.7.4	Handling of containers and equipment				
	5.7.5	Non-dedicated means of bulk transportation				
	5.7.6	Minimum contamination test				
	5.7.7	Unintentional contamination of AdBlue				
	5.7.8	Physical conditions during transportation and storage				
	5.7.9	Loading or unloading				

7 Qualification requirements on AdBlue® auditors

Basic requirements for auditors are described in DIN EN ISO 19011 and have to be considered. AdBlue®-auditors have to be independent and neutral against the audited organizations. Therefore employees of AdBlue® producers or any other organization of the AdBlue® distribution chain cannot act as an AdBlue®-auditor, caused by competition prejudice; this applies to employees of OEMs as well (= potential buyers).

AdBlue®-auditors should have completed a general education in audit principles, procedures and techniques. This is to ensure that audits are conducted in a consistent and systematic manner. Typical providers offering such an education are DGQ, VDA or other institutes, organized in the EOQ.

In order to enable the AdBlue®-auditor to comprehend the scope of the audit and to apply audit criteria he should have knowledge and interpretation skills in organizational structures, management systems and reference documents.

AdBlue®-auditors should have a work experience of at least 3 years that contributes to the development of the knowledge and skills described above. This work experience should be in a technical, managerial or professional position involving the exercise of judgment, problem solving and communication with other managerial or professional personnel, peers, customers or other interested parties.

Applicable laws, standards (ISO 22241 in particular) and the requirements of the present guideline should be well known by the auditor. VDA QMC offers specific training to give future AdBlue®-auditors the chance to deepen this knowledge.

AdBlue®-auditors should have professional skills in audit leadership to facilitate the efficient and effective conduct of the audit.

VDA QMC will approve the knowledge and experience of future AdBlue®-auditors during the training. Every future auditor has to fulfill such training before starting with auditing. The positive closure of the training will be documented with a certificate, issued by VDA QMC. This symbolizes the accreditation of the auditor to conduct AdBlue®-audits in accordance to the present guideline. The accreditation is valid for 3 years.

Prolonging of the accreditation has to be applied at VDA QMC with a specific form. Inquirer has to state how many audits and how many audit days have been carried out by him during the last 3 years.

VDA QMC supervises the ongoing audit results and ratings by checking the audit documentation before issuing the audit certificates (see chapter 4). This implies a second indicator for auditor's reliability and quality of work.

8 Abbreviations and glossary

AUS 32	Aqueous Urea Solution 32.5%
CDS	Coupling Device System
IBC	Intermediate Bulk Container
ISO	International Organization for Standardization
NOx	A type of nitrogen oxide, an air pollutant
OBD	On Board Diagnostic-system
SCR	Selective Catalytic Reduction
Urea	Organic compound with the chemical formula $(\text{NH}_2)_2\text{CO}$
VDA	Verband der Automobilindustrie
VDA QMC	Quality Management Center in Verband der Automobilindustrie

9 Changes

Version 1.5	<ul style="list-style-type: none">- Chapter 4.4: Table on page 18 changed concerning the weighting of criteria 5.4.5 and 5.4.6 from B to A.- Chapters 5.4.5 and 5.4.6 on page 30 changed concerning the weighting from B to A.	13.09.2010
-------------	---	------------