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| **Critical characteristics** are a sub-division of special characteristics. Non-conforming critical characteristics may result in an immediate risk to life and limb from the product or noncompliance with legal regulations (extract from VDA Volume 1). | |
| Supplier:       Audit date:  Audited area:        Audit-No.:  Product/-group:       Auditor(s): | |
| **Parts with critical characteristics (Selection)** Description BRP, Mat.-No., Modification Index | **Critical characteristics** |
|  |  |
| **Audit Result:** | |
| Number of requirements evaluated with „no compliance“: | Number of requirements evaluated with “predominant compliance” |
| **Essential audit findings / conclusions:** | |
| Actions necessary:  yes  no | Date for action plan: |
| Containment actions necessary:  yes  no | (see explanation on page 2) |
| Containment actions implemented:  yes  no | **If not: BRP is informed!** |
| The system review was carried out on the parts listed above. The supplier confirms that the system described is used for all supplied parts with critical characteristics. Corrective actions must be completed by the set date. | |
| **Signature Auditee(s):**    Name / Position: | **Signature Auditor(s):**    Name / Position: |
| **Distribution:** | |

|  |  |
| --- | --- |
| **Evaluation standard** | |
| **Result found for the single requirements:** | **Evaluation** |
| All requirements are **completely fulfilled** | **Full compliance** |
| **More than about ¾** of all requirements have been proven effectively and there is **no special risk** | **Predominant compliance** |
| The requirements are **not** or **not adequately** fulfilled. | **No compliance** |
| For every part listed on the previous page compliance with the checklist’s requirements is compulsory.  If a requirement is regarded as not applicable (n.a.), the reason must be explained for every single case.  There is a **special risk**, if deviations have direct influence on the product quality which may result in products not meeting the specified requirements.  **Deviations and corrective actions:**  If there is no full compliance for a question (evaluation “predominant compliance“ or „no compliance“), corrective actions for the deviations with date and persons in charge must be defined, implemented and their effectiveness must be proven.  If deviations are identified, which bear a special risk (e.g. inadequate measuring equipment used for the inspection of critical characteristics) containment actions must be taken (e.g. exchange of the inspection equipment or external inspection) to guarantee the immediate assurance of the product quality.  **If sufficient containment actions are not possible, BRP must be informed immediately!** | |

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| **1** | **Systematics and documents** |  |
| **1.1** | **There is a procedure for the handling of critical characteristics, which fulfill the requirements of VDA volume 1 and the BRP guideline BIS1000.**  Manual, process - and work instructions, etc. VDA volume 1 and BIS1000 are available. | full  predominant  no  compliance |
| **1.2** | **The technical documents for products with critical characteristics are available with a valid modification index, they are marked as documents with special archiving and the critical characteristics are particularly identified.**  Drawings, technical specifications, performance specifications, requirement specifications, quality assurance agreements, inspection specifications, etc. | full  predominant  no  compliance |
| **1.3** | **The supplier identifies and documents also those characteristics which are not identified as critical characteristics in the BRP documents, but which are regarded as relevant for product safety or compliance with legal regulations, in the context of the supplier’s product responsibility.** | full  predominant  no  compliance |
| **2** | **Personnel** |  |
| **2.1** | **Members of the management and executives are trained in the basic principles of product liability.**  Proven external qualifications about at least one member of management at juridical experts (seminars, lawyers) as well as proven internal knowledge transfer. Qualification of the process manager. Knowledge of national and international law (e.g. EU, USA, Japan) | full  predominant  no  compliance |
| **2.2** | **Personnel, who defines / takes over / influences / inspects / confirms critical characteristics is aware of the handling and the importance of products with critical characteristics, as well as of their responsibilities.**  Manual, circular letter, process – and work instructions, training certificate, etc. | full  predominant  no  compliance |
| **2.3** | **The qualification of personnel who inspect critical characteristics or who are responsible for processes influencing special characteristics is proven.**  Defined personnel for the corresponding tasks. Technical qualification, e.g. for crack detection, heat treatment, metallurgical inspections and laboratory tests. Regularly eye tests / [ophthalmologic](http://dict.leo.org/se?lp=ende&p=/NZNU.&search=ophthalmologic) examinations for personnel who execute visual inspections on critical characteristics (such as x-ray, microscope inspection, magnaflux). Proven by certificates or training records. | full  predominant  no  compliance |
| **3** | **Products and Process** |  |
| **3.1** | **Critical characteristics and related processes and inspections are marked and adequately evaluated in the FMEA and appropriate actions for process assurance are defined.**  Are all processes and risks - including logistic processes and risk of permutation – considered ? Is the level of detail adequate ? | full  predominant  no  compliance |
| **3.2** | **Manufacturing processes and inspections for critical characteristics are clearly indicated in the documents for production planning, -control and -monitoring.**  In control plans, inspection plans, production plans, documents, etc. | full  predominant  no  compliance |
| **3.3** | **All important production parameters for critical characteristics are defined in writing and the production devices are positively controlled and / or continuously monitored for these parameters (proof).** | full  predominant  no  compliance |
| **3.4** | **Process capability for critical characteristics is proven. If there is no proof for process capability, there are records available about 100% inspections.** | full  predominant  no  compliance |
| **3.5** | **The inspection methods for failure detection are adequate for critical characteristics.**  Inspection method, inspection frequency, inspection workflow, use of SPC, inspection equipment with adequate correctness according to the tolerance, Measurement System Analysis, inspection equipment monitoring etc. | full  predominant  no  compliance |
| **3.6** | **There are sufficient regulations and measures to ensure that faulty parts are definitely separated.** | full  predominant  no  compliance |
| **4** | **Documents and records** |  |
| **4.1** | **Process documentation: The necessary documents and records are defined to provide a complete survey of the manufactured quality and are the documents comprehensive, reasonable, protected against alteration and unambiguous.**  **Specifications (*describe* requirements for products and processes):** e.g. drawings, control plans, inspection plans, production plans, specification of process parameters (each with distinct identification and modification level) **Records:** **(*give evidence* that specifications have been fulfilled):** e.g. initial approvals, approval of modification, inspection reports (reference / actual values), capability studies, records about inspection equipment control, audit reports, reliability tests, notes about divergent results with corrective actions (each with distinct reference to the related product or process). | full  predominant  no  compliance |
| **4.2** | **The documents and records concerning production and inspection are filed safe and according to retention period.**  Considering the requirements for archiving media and data processing systems according to VDA Volume 1. Protection from loss (theft, fire, water), protection against unauthorized access and subsequent modification. Particularly protected rooms, duplicates in remote places, microfilming. **Retention period for** **specifications**: 15 years after discontinuation of the product for series- and spare parts demand or after modification of the document. **Retention period for** **records**: 15 years with delivery of the product, to which the records and referring  process belong to. | full  predominant  no  compliance |
| **4.3** | **Traceability is guaranteed for products with critical characteristics and the filing system allows immediate access to relevant documents and records.**  The filing system must enable the assignment of products and inspection documents to the lot-/ batch-no. throughout the entire production chain, including subcontractors. Production period, production conditions, lot-/ batch-no., product master data, production-/ delivery date, delivery note-no, indication on the part, etc. | full  predominant  no  compliance |
| **5** | **Subcontractors** |  |
| **5.1** | **Subcontractors, which influence critical characteristics, are obliged to keep alike systematics for documented evidence of conformity.**  e.g. contract, quality agreement | full  predominant  no  compliance |
| **5.2** | **Subcontractors, which influence critical characteristics, are evaluated and there is evidence for compliance with the requirements concerning critical characteristics.**  e.g. inspection certificate, audit report, visit report | full  predominant  no  compliance |