



## **Manufacturing Process Audit**

*\* Example Report \**

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# Manufacturing Process Audit

Rev.

## GUIDELINES

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**PURPOSE:** Audit scores are rarely understood outside of the quality organization or the auditing company. This audit is based on defined criteria for each element assessed. Scoring is based upon the suppliers ability to meet all of the requirements of this audit, plus any specific requirements of the client. The audit focuses on the manufacturing process and its related supporting functions. The intent of the Process Audit is to provide the client with information useful in making sourcing decisions and reducing associated risks.

**CLIENT CHECKLIST - PROCESS CHECKLIST:** Either a client checklist or a product/process checklist may be included with the audit. The auditor will review the questions and use the responses to score questions in the survey.

### SCORING:

Scores are assigned based on what is done for the Pro QC client regardless of what is done for other clients. For example, if control plans are developed for other clients but not for the Pro QC client, the score must be NC. Scoring must be explained to the supplier at the opening meeting.

Complies with the Requirements = C

Improvement Needed = I

Non-Conformance Found = NC

N/A = Does **Not** Apply

### GUIDELINE FOR SCORING CONFORMANCE:

Each question is assessed for conformance to the requirements of ISO 9001, and the auditors knowledge of the product and/or process. This must be clear to the supplier at the opening meeting.

Complies with Requirements =

- has objective evidence to support the question, AND
- has a written procedure (when required).

Improvement Needed =

- has objective evidence but procedure needs improvement.
- has objective evidence, but no written procedure.
- has written procedure, but is lacking some objective evidence to support the question.

Non-Conformance =

- No objective evidence to support the question (regardless of the procedure).
- Lacking some objective evidence and no written procedure.

### AUDIT REPORT:

- Scope of the Audit
- Recommendations
- Strengths of the Supplier's Quality System and Manufacturing Process
- Opportunities for Improvement (Weaknesses in the Supplier's Quality System and/or Manufacturing Process)

### RESULTS REVIEW WITH SUPPLIER:

The auditor should review the audit results with the supplier, but cannot provide the supplier a copy of the audit. The audit is the property of the client.

### CORRECTIVE ACTIONS:

It is recommended that the client request a corrective action (improvement plan) based on the results of the audit. The improvement plan should include the following:

- Detailed description of action plan.
- Name of the person responsible for the improvement activity.
- Date when the improvement will be completed.



# Manufacturing Process Audit

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## SUMMARY

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Supplier Name XXXXXXXXXXXXXXXXXXXXXXXXXX	Audit Date XX/XX/XXXX	Report No. IEC00000372H
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SUPPLIER'S INFORMATION	CLIENT'S INFORMATION
NAME : XXXXXXXXXXXXXXXXXXXXXXXX	NAME : XXXXXXXXXXXXXXXXXXXXXXXX
ADDRESS : XXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXX	ADDRESS : XXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXX
CITY : XXXXXXXXXXXXXXXXXXXXXXXX	CITY : XXXXXXXXXXXXXXXXXXXXXXXX
COUNTRY : XXXXXXXXXXXXXXXXXXXXXXXX	COUNTRY : XXXXXXXXXXXXXXXXXXXXXXXX
PHONE : XXXXXXXXXXXXXXXXXXXXXXXX	PHONE : XXXXXXXXXXXXXXXXXXXXXXXX
FAX : XXXXXXXXXXXXXXXXXXXXXXXX	FAX : XXXXXXXXXXXXXXXXXXXXXXXX

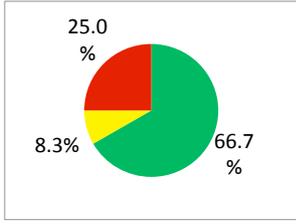
SUPPLIER'S PERSONNEL PARTICIPATING			
Mr./Mrs. XXXXXXXXXXXXXXXXXXXXXXXX	Title: XXXXXXXXXXXXXXXXXXXXXXXX	Email: XXXXX@XXXXX	
Mr./Mrs. _____	Title: _____	Email: _____	
Mr./Mrs. _____	Title: _____	Email: _____	
Mr./Mrs. _____	Title: _____	Email: _____	
Mr./Mrs. _____	Title: _____	Email: _____	
Mr./Mrs. _____	Title: _____	Email: _____	
Mr./Mrs. _____	Title: _____	Email: _____	

PRO QC PERSONNEL PARTICIPATING			
Mr./Mrs. XXXXXXXXXXXXXXXXXXXXXXXX	Title: XXXXXXXXXXXXXXXXXXXXXXXX	Email: XXXXXXXXXXXXXXXXXXXXXXXX	
Mr./Mrs. _____	Title: _____	Email: _____	
Mr./Mrs. _____	Title: _____	Email: _____	

Scope : \_\_\_\_\_ Factory Profile, Manufacturing Process Audit

### AUDIT RESULTS

Category	Nb. Ques.	%
Complies with Requirements ( C )	24	66.7%
Improvement Needed ( I )	3	8.3%
Not-compliant with Requirements (NC)	9	25.0%
Not Applicable (N/A)	6	



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### RECOMMENDATIONS

- The process is effective. You could start or continue business with this supplier.
- The process is acceptable, with minor nonconformities. YOU could use this supplier, and keep pushing for improvements.
- The process has several major issues noted. You could temporarily use this supplier and request immediate corrective action in case of long-term business.
- There are serious major issues noted with this supplier that could impact in your business. The better solution will be to source for another supplier.



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## AUDIT REPORT

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Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXXXXXXXXX	XX/XX/XXXX	IEC00000372H

**Scope of Audit:**

To evaluate the factory's production control process and identify risk areas and opportunities for improvement by predicting failure opportunities within the manufacturing, and related processes.

**Summary/Recommendations:**

1. The supplier is a middle size foundry with a long history. Supplier is ISO9001 certified. See photo 29 for reference.
2. The founding equipments are acceptable. Arc furnaces, automatic molding machines and core making machines included. See photos 11, 12 & 13 for reference.
3. The supplier can do chemical analysis and mechanical property testing. See photos 15, 16, 17 & 18 for reference.
4. The supplier has machining & heat treat capability. See photos 6, 7 & 8 for reference.
5. The supplier has the founding experience of similar parts to 8100370, 8100371 & 8100372. See photos 4 and 5 for reference.
6. When the audit was performed, the client's parts had not been produced. This audit did not focus on client's parts, but on similar castings.
7. For MTC issued by BAM, see photo 28.

**Strengths:**

1. Good founding equipment and heat treat capability.
2. Sufficient test equipment, chemical analysis and mechanical property test machine.
3. Founding experience of similar part.

**Opportunities for Improvement:**

1. Sub-supplier approval and evaluation program should be developed.
2. More detailed quality control plan or inspection instruction for all parts should be developed. Significant characteristics should be identified.
3. The on-time delivery should be monitored. The statistics and objective of on-time delivery should be developed.



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## AUDIT CHECKLIST

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Supplier Name XXXXXXXXXXXXXXXXXXXXXXXXXX	Audit Date XX/XX/XXXX	Report No. IEC00000372H
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C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

QUESTIONNAIRE	FINDINGS	SCORE
<b>SECTION 1 - TECHNICAL DOCUMENTATION</b>		
Does the supplier have all of the required technical documentation necessary to the part or product being reviewed? Examples include drawings, specifications, material charts, regulations, reference samples, CAD Data, etc.	The drawings and specifications have been received by the supplier. The technical engineers are now reviewing all of the documents.	C
The technical documentation for the part, product, or component being reviewed may include and not limited to: - Drawings - Specifications/standards for material, testing, and laboratory, etc.		
What is the supplier's document control program, and is it effectively implemented?	There is a very detailed file control program. All the documents are well controlled by a specific person.	C
The supplier shall have a document control program. The program must ensure: - Proper revision level - Distribution of new revision - Control of obsolete documents - Records retention		
How are significant characteristics selected, classified and identified?	No significant characteristics were selected and identified. The supplier always checks all of the characteristics equally.	NC
The supplier must have a method to identify significant product and process characteristics. The characteristics shall be visible in all technical documentation (flow chart, control plan, work instruction, etc.). When the technical documentation supplied by the customer does not indicate the existence of significant characteristics, the supplier's personnel shall be trained and able to identify those characteristics important to the customer or product by means of techniques such as process FMEA's, DOE, knowledge of their processes, and/or knowledge of how the product is used. <i>At a minimum, the supplier must select characteristics that affect close tolerances, fit, function, finish, reliability, durability or characteristics affected by their manufacturing process and process parameters.</i>		
Are the required technical documents available at the workstation?	There are working instructions at all workstations. See photo 21 for reference.	C
The required technical documentation shall be available at the workstations and/or easily accessible without disrupting the work activity.		
<b>SECTION 2 - CONTROLS AND TESTS ON PURCHASED PARTS</b>		
Is there a list of qualified sub-suppliers? What is the supplier's program to approve new sub-suppliers for business?	There is no sub-supplier list, and no approval program for new sub-suppliers.	NC
- The supplier must have a list of approved sub-suppliers they can purchase raw material or services from. - The supplier must have a procedure that describes how new sub-suppliers are approved. This includes: • Criteria for evaluating new sub-suppliers • Rules for issuing purchase orders based on the sub-supplier's performance • Specification of purchase data to send to the sub-supplier • Acceptance/verification criteria for the purchased parts, raw material, etc • Rules for how to handling of non-conforming parts received NOTE: The auditor must record the names of sub-suppliers reviewed.		



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QUESTIONNAIRE	FINDINGS	SCORE
<p>How is sub-supplier performance evaluated using the information gathered for the receiving inspection function?</p> <ul style="list-style-type: none"> <li>- The supplier must have a procedure to monitor the performance of their sub-suppliers. Performance metrics should include:</li> <li>- On-Time-Delivery</li> <li>- Quality of delivered parts - Parts Per Million or Shipment rejects should be used</li> <li>- Effectiveness of corrective actions</li> <li>- There should be established objectives for each metric with action plans when objectives are not met</li> <li>- The supplier must be able to work with the sub-suppliers in terms of:</li> <li>- auditing the sub-supplier for each new product/ process</li> <li>- analysis of Control Plans for new or modified parts</li> <li>- analysis and monitoring of the improvement plans following a non-conformance</li> </ul> <p>NOTE: The auditor must record the names of sub-suppliers reviewed.</p>	<p>The sub-suppliers' performances were evaluated.</p>	NC
<p>If a sub-supplier is not approved, what prevention controls are used to ensure the conformity of the supplied product and/or raw material?</p>	<p>Each lot of incoming material was inspected before being accepted. For example, the factory will do chemical analysis on every incoming lot of pig iron. See photo 27 for ref.</p>	C
<p>When it is necessary to purchase from non-qualified sub-suppliers that do not satisfy the requirements of elements 2.1, effective controls, using an adequate sampling plan, shall be used in both the incoming inspection area and during the manufacturing process to prevent/block the use of non-conforming parts or raw material. Whenever possible, this should include the use of statistical controls on the product.</p> <p>NOTE: How is this applied? Must see examples. NOTE: Is the sampling plan based on C = 0? Please document here.</p>	<p>First, the supplier will review the certificates of all incoming materials. Next, the supplier will verify the results on the certificate by sending the material to an independent lab.</p>	C
<p>How does the supplier control the quality of incoming material / raw material that is not subject to controls by receiving inspection?</p> <ul style="list-style-type: none"> <li>- Selected types of material/raw material may not be subject to controls at receiving inspection, such as:</li> <li>- Sheet metal</li> <li>- Bar stock</li> <li>- Plastic raw material</li> <li>- The supplier must receive documentation/certification with results of inspection and tests for each delivered lot. e.g. chemical analysis, physical analysis, conformance reports.</li> <li>- The supplier should verify the results reported on the 'certifications' by an independent laboratory. Minimum of annually.</li> </ul>	<p>The supplier failed to show MTC from sub-suppliers. The supplier explained they would do a chemical analysis on every lot of incoming pig iron.</p>	I



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QUESTIONNAIRE	FINDINGS	SCORE
<p>- Before starting production, the supplier shall receive and approve samples submitted by the sub-supplier. The samples for part approval must be:</p> <ul style="list-style-type: none"> <li>- Manufactured from the actual production tooling</li> <li>- Checked for conformity to the specifications</li> <li>- And is compatible with the suppliers' processes and use on the customers' final product</li> </ul> <p>- The part approval must verify the conformity of the material to the technical specification.</p> <p>- When a part is obtained from multiple molds, dies or multi-cavity equipment, each mold/die/cavity shall be identified in a permanent way on the part. A separate sampling shall be provided for each in order to carry out separate dimensional controls. This shall also be required for parts of the same size but different features (color, hardness, embossing, etc.).</p> <p>- If the approval is granted via deviation, this shall be temporary and shall indicate the quantity or the valid time period.</p> <p>- Deviation on characteristics that may affect the fit or functionality of the component as seen by the customer shall be authorized in advance by the customer's specific function (dept).</p>		I
<p><b>CONTROL PLANS / INSPECTION INSTRUCTIONS</b></p> <p>2.6) Are Control Plans (or equivalent documents) available at Receiving Inspection, updated, and fully developed (adequate)?</p> <ul style="list-style-type: none"> <li>- Control plans and/or inspection instructions, compliant with updated drawings, safety, and significant characteristic classifications, shall be available for all purchased parts.</li> <li>- The Control Plans must be updated based upon:               <ul style="list-style-type: none"> <li>- the results of non-conformances found</li> <li>- the results of corrective actions implemented.</li> </ul> </li> <li>- The Control Plan <u>must give all information necessary to guarantee the conformity of the part or raw material.</u> It must include: characteristics to inspect; specification/tolerance; quantity; frequency; evaluation or measuring technique; recording/analysis method; reaction plan.</li> <li>- The supplier must have a <u>defined sampling plan.</u> The sampling plan should be <u>based on zero defect acceptance;</u> if one defective part is found in the sample lot, the entire lot must be rejected.</li> <li>- The <u>classification of product characteristics shall be indicated on each control plan</u> or inspection instruction. (Significant/critical/safety) This shall be compliant with the technical specifications and/or preventive analysis performed on the product when requested (Design and/or Process FMEA.).</li> </ul>	<p>There are incoming inspection specifications for all incoming parts, but the characteristics are not classified.</p>	I
<p><b>SUFFICIENT GAGES AT RECEIVING INSPECTION</b></p> <p>2.7) Is the required inspection and test equipment available and suitable?</p> <p>There shall be available the required types of inspection and test equipment to perform the necessary inspections (personal gages included).</p> <ul style="list-style-type: none"> <li>- Gages shall be of adequate measuring class commensurate to the requirements of drawings, regulations and importance of the features.</li> <li>- Gage identification, calibration status and expiration date shall be ensured; e.g. calibration stickers on gages and test equipment.</li> <li>- Gages maintenance/protection conditions shall be available at the workstation.</li> <li>- Reference samples (template, master, etc) used to verify the operating condition of gages and inspection/test equipment (e.g. hardness tester, profilometer) shall be available, identified, maintained, and correctly stored.</li> <li>- Reference samples shall be used according to the frequencies stated in <u>the control plans or per the manufacturers' recommendation.</u></li> </ul>	<p>Yes, there are a lot of different kinds of measuring tools and gages and all with calibration stickers and well kept. See photo 15, 16, 17, 18, 19 &amp; 20.</p>	C



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QUESTIONNAIRE	FINDINGS	SCORE
<p>How do the receiving inspectors identify and separate material in the receiving inspection area?</p> <ul style="list-style-type: none"> <li>- There must be product identification areas and/or visual identification system (color coded tags) that guarantees the separation of product according to the different kinds of inspection status, e.g.               <ul style="list-style-type: none"> <li>- Product waiting to be checked; or subject to Receiving Inspection Hold</li> <li>- Accepted product, or 'Free Pass'</li> <li>- Product waiting for a decision (possible non-conformance)</li> <li>- Rejected product</li> </ul> </li> <li>- The receiving system shall ensure that the parts received are cross-referenced to the shipping documents (part number, heat number, code number, quantity) to ensure the correct material is received.</li> <li>- All boxes, cartons, crates shall show the identification code, manufacture/shipment date, testing status etc.</li> <li>- A quarantine area must be identified.</li> </ul>	<p>The supplier always does the incoming inspection immediately on parts' arrival to the workshop. Only parts that pass incoming inspection can be accepted, and failed parts will be returned.</p>	N/A
<p>How are non-conforming products managed at the Receiving Dock and Receiving Inspection areas?</p> <ul style="list-style-type: none"> <li>- Adequate procedures shall be provided and applied defining the activities necessary to control any non-conformance parts discovered at the Receiving Dock or Receiving Inspection area.</li> <li>- A suitable area shall be identified for the segregation of any non-conforming material and/or products awaiting a decision, with appropriate product identification.</li> <li>- There shall be specific procedures for the management of the corrective action that will be managed in terms of root cause analysis, implementation, responsibility, effectiveness, timeliness and with the involvement of the sub-supplier.</li> <li>- In case of non-conformities, timing for implementation of the corrective action shall be defined.</li> <li>- Data concerning the non-conformity of purchased products shall always be recorded and shall be used as part of the supplier evaluation criteria. See 2.1.</li> </ul>	<p>The supplier always does the incoming inspection immediately upon parts' arrival to the workshop. Only parts passing the incoming inspection can be accepted, and failed parts will be returned.</p>	N/A
<p>How does the suppliers' program achieve the proper handling, storage, preservation of received parts and rotation of stock?</p>	<p>There is a Warehouse Management Program. The materials in the warehouse are in good condition, and the materials' information kept in the computer is sufficient.</p>	



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QUESTIONNAIRE	FINDINGS	SCORE
<ul style="list-style-type: none"> <li>- Handling, transport and containing means (forklifts, transpallets, etc) shall be appropriate to handle the received material, and operated under safety conditions.</li> <li>- Containers shall be suitable, clean, free from any old identification, and guarantee the on-going integrity of the parts.</li> <li>- Stocking shall be done on pallets, shelves etc; these shall be suitable and in good conditions: cleaning, maintenance, safety, complying with the maximum piling to ensure safety and product integrity</li> <li>- Storage/stockpiling areas shall be sufficiently sized to contain the material, located in a logical way with respect to the flow, adequate to contain and protect the product, with easy access and safe handling.</li> <li>- There shall be a system guaranteeing FIFO (according to aging).</li> <li>- Product subject to expiration dates must be identified and properly stored to guarantee its product integrity; e.g. paint, chemicals, glue/adhesives, rubber O-rings, seals, etc.</li> <li>- There shall be a system for tracking expiration dates of perishable materials in stock, with notification of materials approaching the expiration date.</li> <li>- Product subject to environmental controls must be properly stored to ensure its product integrity. i.e paint</li> <li>- Legal indications for toxic products, statutory provisions for noxious/toxic products, and expiration date, etc. shall be clearly indicated on containers and the individual items within the container.</li> </ul> <p>NOTE: Auditor should check the technical sheet to verify how the product</p>		C
<b>SECTION 3 - MANUFACTURE</b>		
<p>Does the supplier meet the requirements contained within the commodity checklist? If there is not a client specific checklist, the question is not applicable, score "N/A."</p>	<p>There is no client specific checklist.</p>	N/A
<ul style="list-style-type: none"> <li>- The auditor shall use the appropriate checklist of questions for the commodity being reviewed.</li> <li>- The supplier shall demonstrate proficiency in all areas being reviewed.</li> <li>- The supplier shall demonstrate the effectiveness of the controls used to monitor their processes.</li> </ul>		
<p>How does the supplier Use APQP to ensure all relevant requirements are considered, developed and implemented?</p>	<p>There is no APQP available. The supplier explained they would not make APQP unless the client requires it.</p>	



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QUESTIONNAIRE	FINDINGS	SCORE
<ul style="list-style-type: none"> <li>- Customer needs, expectations and requirements must be determined, fully understood, and converted into product and process requirements with the aim of achieving customer confidence.</li> <li>- A preliminary analysis shall be conducted on the manufacturing activities, aimed at the identification and prevention of defects, such as Process FMEA.</li> <li>- The supplier shall identify and select the significant product and process characteristics. See 1.3 above.</li> <li>- Control plans shall be consistent with the results obtained in the PFMEA in terms of size, frequency etc.</li> <li>- Before starting production on new or revised product, the suitability of all production factors shall be analyzed in a documented manner. Product Realization Planning should detail all of the activities necessary for preparing for, organizing, and implementing production, and it should include:               <ul style="list-style-type: none"> <li>- Ensuring all drawings, standards, and specifications are available</li> <li>- Defining production methods and the process flow</li> <li>- Preliminary analyses, e.g., PFMEA</li> <li>- Defining the process and product parameters to be controlled</li> <li>- Defining statistical methods and validation of process capability</li> <li>- Developing control plans</li> <li>- Defining the requirements and methods for traceability</li> <li>- Defining evaluation and test methods</li> <li>- Purchasing, accepting and installation of equipment and machinery necessary for production</li> <li>- Setting up systems for movement, storage, packing and shipping</li> <li>- Preparing production documents, e.g. set-up, operator, and inspection instructions, etc.</li> <li>- Personnel training</li> <li>- Preparation of samples and pilot production</li> </ul> </li> <li>- For each of the above, responsibilities and timelines must be established.</li> <li>- Manufacture of trial lots to record all the significant parameters and results achieved, with particular reference to the process capability indexes.</li> </ul>		NC
<p>Prior to release into production, how does manufacturing engineering verify the performance of the process(es), and are improvement actions implemented when necessary?</p> <ul style="list-style-type: none"> <li>- A preliminary analysis must be conducted on the manufacturing process to ensure it can produce parts that meet the specification and prevent defects.</li> <li>- Prior to release into production, the supplier's manufacturing engineering function (or equivalent function) shall verify the capability of the tooling and/or process.</li> <li>- The supplier must ensure the ability of the tooling and/or process to produce parts that conform to the print specification.</li> <li>- The supplier should conduct short term capability studies to ensure the potential long term capability of the tooling and/or process.</li> <li>- Preliminary process capability objectives must be defined. Acceptable values must result &gt; 1.66 Process Potential studies. If the process is 'not capable', the process must be improved to meet the objective or a more reliable process must be developed. The effectiveness of the improvements must be verified.</li> <li>- Capability must be determined under the normal production conditions using the normal production tooling and processes.</li> </ul>	No process analysis will be done unless the client requires it.	NC
Does the supplier receive customer approval prior to the initial start of production, and does the process currently being utilized match the process approved by the customer?	The supplier did not receive any PPAP requirement from the client. No PPAP will be done unless the client requires it.	



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QUESTIONNAIRE	FINDINGS	SCORE
<p>- Before starting production, the supplier shall receive part approval on samples submitted to the customer.</p> <p>- The supplier may not change processes from what was previously approved by the customer.</p> <p>NOTE: Samples must be produced on the actual production tooling using normal production conditions. Part approval must ensure that the samples produced meet all of the requirements of the part drawing, technical specifications, and is compatible with the customers' processes and use on the final product.</p> <p>When a part is obtained from multiple molds or dies or multi-cavity dies, each mold/die/cavity shall be identified in a permanent way of the part, and a separate sampling shall be provided for each of them in order to carry out separate dimensional controls.</p> <p>A separate sampling is also required for parts of the same size but different features (color, hardness, embossing, etc.). The conformity of material to the technical specification shall be verified.</p>		N/A
<p>Are set-up and operator instructions complete, adequate, updated and understandable in content, and do they ensure the information is complete for the correct performance of activities, and are they available at the workstation?</p> <p>- Each workstation must have access to clear instruction documents describing, in accordance with requirements, the set-up, the operations to be carried out, and the means to be used. The documents must be subject to revision control and they must correspond to relevant drawings/specifications.</p> <p>- Workstations shall be provided with operator instructions, and parameter set-up instructions according to the needs and method of production. During the planning and development of these instructions, special attention should be given to operations where inspections occur.</p> <p>- Such documents shall be easily identifiable for the various process steps related to their use (e.g. classification, colors, pictures/sketches/drawings etc.) to avoid any possible mistake.</p> <p>- Whenever necessary parameter values shall be recorded at the start of production; these should be analyzed to verify any drift.</p> <p>- All the gaging, tooling, equipment necessary to the activities described in the instructions shall be available. They shall be adequate and in good operating conditions.</p> <p>NOTE: The auditor must review the documents that are available at the workstations and list them here.</p>	<p>There are drawings and working instructions at all workstations. See photo 21 for reference.</p>	C
<p>Is the control plan available at the workstation? Does it provide adequate information for the scheduled inspections and tests? Is it updated, and does a symbol for significant characteristics appear on the control plan? See 1.3.</p>	<p>There is inspection instruction at the workstations, but it is very rough and no significant characteristics are defined.</p>	



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QUESTIONNAIRE	FINDINGS	SCORE
<ul style="list-style-type: none"> <li>- Control plans and/or Inspection Instruction Sheets shall be developed.</li> <li>- The characteristic to inspect, tolerance/specification, frequency, sample size and methodology of inspection shall be defined.</li> <li>- Acceptable quality levels shall be defined.</li> <li>- A reaction plan for non-conformances shall be defined.</li> <li>- Any significant characteristic shall be designated by the appropriate symbols throughout the Control Plan.</li> <li>- Technical documentation required to conduct inspections (cycles, drawings, instructions etc.) shall be available at each workstation as required.</li> <li>- The supplier must have a defined sampling plan. The sampling plan should be based on zero defect acceptance; if one defective part is found in the sample lot, the entire lot must be rejected.</li> <li>- The method of processing the statistical data shall be defined.</li> <li>- There shall be, where applicable, effective error-proofing systems or automatic inspections** for detecting non-conforming parts and the stopping of production and/or reject for all significant characteristics; particularly for those where 100% control is required.</li> </ul> <p>NOTE (**)</p> <ul style="list-style-type: none"> <li>- Error proof or 100% control, shall imply that the detection and rejection of parts are performed in an automatic way.</li> <li>- 100% "non-objective" control by the operator is acceptable if:               <ol style="list-style-type: none"> <li>1) The personnel are trained, have available the required inspection and test equipment, and are working in ideal working conditions (rotation, lighting, etc.).</li> <li>2) The conforming part is traceable back to who performed the inspection.</li> <li>3) There is a periodic audit to ensure that the inspection is 100%</li> </ol> </li> </ul>		I
<p>In the production start-up/set-up phase, how is conformance to the specifications assured?</p> <ul style="list-style-type: none"> <li>- Controls on the first part produced shall be defined and implemented in the case of:               <ul style="list-style-type: none"> <li>- Start or re-start of production</li> <li>- After part modification</li> <li>- Or change of manufacturing process</li> </ul> </li> <li>- Conformance to specification shall be guaranteed through</li> <li>- Ensuring the availability of production tools, operating instructions, inspection instructions or control plans, and handling equipment</li> <li>- Verification that the part is produced with production tooling</li> <li>- Part approval by appointed personnel with specific approval instructions (cannot be the same person that set-up the job). The instructions shall be available, correct and complete.</li> <li>- "OK to Produce" is only given after verification of part conformity to specifications.</li> <li>- Ensuring the related documentation concerning parts is available.</li> <li>- When applicable, availability at working station of approved master sample part. See 3.9.</li> </ul>	<p>The inspector will check the first three parts when production starts/re-starts or any changes to manufacturing process.</p>	C
<p>Is the required inspection and test equipment available and suitable for each inspection and test area, and are they properly calibrated with reference to expiration date of periodic calibration and maintenance status?</p>	<p>The gages and toolings are in good condition. All the gages are within next calibration date and have a calibration tag. See photos 15, 16, 17, 18, 19 &amp; 20 for reference.</p>	C



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QUESTIONNAIRE	FINDINGS	SCORE
<ul style="list-style-type: none"> <li>- There shall be a sufficient quantity of inspection and test equipment to carry out the necessary controls (personal gages included).</li> <li>- Equipment shall be commensurate to the development of the product specifications.</li> <li>- Gages shall be of adequate measuring class commensurate to the requirements of drawings, regulations and importance of the features.</li> <li>- Availability, suitability, identification, efficiency, correct storage of gages and test equipment shall be ensured.</li> <li>- Availability, suitability, identification, efficiency, correct storage of reference samples shall be ensured.</li> <li>- The supplier shall have a written, and properly applied, procedure to audit the capability of the gages for: accuracy, repeatability, reproducibility and stability.</li> <li>- The consistency between capability of the gages and tolerances shall be audited.</li> <li>- There shall be a gage calibration system, including calibration frequency and recording of relevant results.</li> <li>- All gages owned by employees must be included in the gage calibration program.</li> <li>- All jigs, fixtures, templates, etc used to ensure/check the quality of parts must be included in the gage calibration program.</li> <li>- Gage identification, calibration status and expiration date (via: calibration stickers, color code, etc) shall be ensured.</li> <li>- The supplier shall have written work instructions describing how to calibrate each type of instrument.</li> <li>- The criteria adopted to guarantee the continuance of required inspections and tests during the gage calibration period shall be defined (especially when the instrument is sent to external laboratories).</li> <li>- There shall be gage history cards containing start-up date, interventions of calibration, 'as found' condition, maintenance, repair, etc.</li> <li>- There shall be gage blocks and/or reference samples for gage calibration; traceable to the national standard.</li> <li>- The appropriateness of the accuracy level of gage blocks and/or samples</li> </ul>		<b>C</b>
<p>Are reference samples and/or written acceptance standards available for the evaluation of the parts with appearance characteristics; and are they used? (e.g. sample parts, color chips, photographic documentation, photometric plates, etc.)</p> <ul style="list-style-type: none"> <li>- A master sample should be available and used for inspection of parts having appearance items.</li> <li>- The master shall be, when applicable, in each inspection/control station.</li> <li>- There shall be evidence of traceability of the master samples.</li> <li>- Storage, handling conditions and preservation of the master samples shall be defined.</li> <li>- The supplier may also use written Acceptance Standards for parts with appearance characteristics. These shall be developed by either the customer or the supplier.</li> </ul> <p>NOTE: For products with appearance characteristics, the supplier could conduct a Gage R&amp;R Study - attribute data to assess the accuracy/ability of their inspectors.</p>	<p>There are detailed appearance check specification including how to detect different kinds of appearance defects.</p>	<b>C</b>
<p>Are operations that use automatic/semi-automatic inspection or error proofing, subject to periodic inspection of functionality through the use of a suitable master (known defective part)? Is the master available at the workstation, and is the master used according to scheduled frequencies?</p>	<p>No error proof system.</p>	<b>N/A</b>



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QUESTIONNAIRE	FINDINGS	SCORE
NOTE: The auditor shall verify the effectiveness of mistake proofing by simulating one or more non-conformities.		
<p>Are results of inspections and tests recorded and filed and do they allow the traceability of parts/products back to the in-process documentation, especially for safety/significant characteristics?</p> <p>NOTE: The record retention period must be consistent with the importance of the characteristics/parts.</p> <ul style="list-style-type: none"> <li>- The supplier shall have a procedure for the identification and retention of quality records (inspection results).</li> <li>- Procedures for storing the documents in suitable places shall be defined and applied.</li> <li>- The supplier must have a procedure ensuring the traceability of products or production lots back to the in-process documentation (inspection results), and when necessary, to the raw material. Product traceability shall be ensured for parts with safety features and/or significant characteristics.</li> <li>- The lot traceability system shall furnish traceability back to               <ul style="list-style-type: none"> <li>- Identity of personnel performing the operations; e.g. set-up; operator; inspector</li> <li>- 1st piece approval - approved by whom?</li> <li>- Processing information</li> <li>- Records of inspections; internal and external</li> <li>- Date of manufacture</li> <li>- Quantity</li> <li>- Manufacturing lot number</li> <li>- Lot of raw material used and sub-supplier, when required</li> <li>- Lot of each component and sub-supplier, when required</li> <li>- Records of inspection and tests must be made available to the customer when requested.</li> </ul> </li> </ul>	<p>The inspection results have been recorded. There are pouring dates on the castings and on the check records. See photo 21 for reference.</p>	C
<p>Are product, parts, semi-finished and raw materials in the production flow correctly identified (e.g. drawing, part number, revision index, lot, casting, etc.)?</p> <ul style="list-style-type: none"> <li>- All semi-finished and/or finished products shall be positively identified (e.g. part number, lot code, quantity) and the progress shall be clearly shown with respect to the different phases of the manufacturing cycle (operations completed).</li> <li>- The application and appropriateness of the provisions to visualize the inspection status (e.g. color coded tags) shall be guaranteed</li> <li>- Product waiting to be inspected</li> <li>- Product inspected and accepted</li> <li>- Product waiting for a decision (possible non-conformance)</li> <li>- Non-conforming product</li> <li>- Waste product (scrap &amp; segregation/identification in order to avoid any reinsertion into the process)</li> <li>- Identification may be related to every single piece, to the container, or the work cell, and shall enable to go back to the information concerning inspections, gages/test equipment, operator, date, team, etc.</li> <li>- Identification shall be clear, even further, to the partial use of the lot.</li> </ul>	<p>Yes, the castings can be identified by pouring date.</p>	C
<p>How does the operator use the inspection results to detect a drift or change in the process?</p>	<p>The operators have not been trained to interpret the inspection data. They never do this.</p>	



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QUESTIONNAIRE	FINDINGS	SCORE
<p>- The supplier's personnel must be trained to interpret the inspection data and/or charts to be able to detect changes to the process.</p> <p>- The supplier shall have a procedure for the immediate action on the process when a 'process drift' or degradation of the process is evident.</p> <p>- Actions taken should be recorded on the appropriate forms.</p>		NC
<p>For any characteristics being inspected or tested, how is the capability of the process proven?</p> <p>- The capability of any process or characteristic being inspected or monitored must be proven initially (see 3.3 above) and monitored periodically on an on-going basis.</p> <p>- The processing method of statistical data must be defined. (Attribute, variables, bilateral, unilateral, etc)</p> <p>- Process capability must be determined under the normal production conditions.</p> <p>- Process capability must be monitored over time to guarantee its ongoing capability; e.g. monthly. The capability index must be compared to previous performance (e.g. matrix comparison chart) and analyzed by manufacturing engineering (or equivalent) for acceptance or improvement actions.</p> <p>- Objectives for process capability must be defined. Acceptable values must be &gt;1.33 for long-term capability. If the process becomes 'not capable', 100% product inspection must be performed. Additionally, the process must be improved to meet the objective or a more reliable process must be developed.</p> <p>- Process/machine parameters subject to significant alterations over time (e.g. temperatures, times, speed, pressures etc.) must be systematically monitored, automatically or manually, with respect to set tolerances.</p> <p>- Special processes must be defined; e.g.: welding, thermal treatments, painting, rubber-metal bonding etc.</p> <p>Definition of influencing parameters and relevant ranges of 'acceptable values' must be documented in detail, and acceptance standards must be developed. Special processes must be re-qualified periodically.</p> <p>- Process qualifications shall be made through destructive tests on the part when necessary.</p> <p>- Analysis of data is not limited to only SPC data.</p> <p>- The percentage of scrap may be used as an indicator of process capability.</p> <p>- Machine capability must be re-calculated when major maintenance is</p>	<p>The supplier will not do process capability analysis unless the client requires it.</p>	N/A
<p>How does the operator verify the ongoing process capability of processes used to produce the significant characteristics listed on the control plans?</p> <p>NOTE: N/A cannot be assigned if the process is used to produce a significant characteristic and/or if it is critical to the subsequent manufacture of a significant characteristic.</p> <p>- In addition to above, process capability for significant characteristics (customer's or the supplier's) must be monitored on a continuous basis.</p> <p>- In the event the results of process capability is less than the objective (e.g. 1.33 for variables data, or 99.73% O.K. for attribute data), the supplier must implement effective controls and improvement actions to ensure no non-conforming parts are sent to the customer, and to improve the process.</p>	<p>No significant characteristic was selected and identified.</p>	NC
<p>What is the operator's reaction when a non-conforming part is discovered?</p>	<p>When a non-conforming part is discovered, the operators will do the following,</p> <p>a) Stop the production</p> <p>b) Identify/mark the non-conforming part.</p>	



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QUESTIONNAIRE	FINDINGS	SCORE
<ul style="list-style-type: none"> <li>- The supplier shall use a system for the easy identification of conforming products already produced (lot breaker, control charts, etc.).</li> <li>- The operator must have the authority to stop production when standard actions on the process are not sufficient to guarantee product conformance (regain process control).</li> <li>- The supplier shall have a procedure to inspect parts back to the last 'in-control' point/part, when a non-conformance is found.</li> <li>- The supplier shall have a procedure to the identification and segregation of non-conforming parts.</li> <li>- Production stops, type of action, corrective action and its effectiveness should be recorded.</li> <li>- If applicable, the customer should be informed.</li> </ul>	<ul style="list-style-type: none"> <li>c) Segregate the non-conforming parts.</li> <li>d) Report to the technical engineer.</li> </ul>	C
<p>Is there a systematic approach to problem solving, and is it monitored for effectiveness?</p> <ul style="list-style-type: none"> <li>- There shall be defined rules for the management of the non-conforming products.</li> <li>- Identification</li> <li>- Segregation</li> <li>- Rework/repair*</li> <li>- Re-check</li> <li>- Reject or Scrap</li> <li>- Deviations</li> <li>- Rules for the management of non-conformances shall be defined/applied. They shall include:</li> <li>- Analysis of non-conformity</li> <li>- Containment actions to prevent defects and suspected products are leaving the supplier plant.</li> <li>- Root cause identification, including use of PFMEA, Cause and Effect Diagram, DOE, etc.</li> <li>- Final corrective actions.</li> <li>- Verification of effectiveness.</li> <li>- Extension of the improvement to similar process that may experience the same potential root cause.</li> <li>- There must be a procedure to request written authorization from the customer prior to implementing a permanent change to the part or process.</li> <li>- Corrective actions to the process shall be used to update FMEA's and control plans.</li> </ul> <p>* Rework = Part fully meets the print requirements. e.g. enlarge undersize hole. Repair = Part does not meet print requirements but may be usable. e.g. weld close an oversized hole then re-drill to proper size</p>	<p>There is documented program for corrective actions, and it was well implemented. The supplier can show examples.</p>	C
<p>Is there written procedure for the re-inspection of parts prior to release back into the production process?</p> <ul style="list-style-type: none"> <li>- There must be a procedure to request written authorization from the customer prior to any repair operation.</li> <li>- The reworked/repared products shall be re-inspected prior to release back into the process flow.</li> </ul> <p>* Rework = Part fully meets the print requirements. e.g. enlarge undersize hole. Repair = Part does not meet print requirements but may be usable. e.g. weld close an oversized hole then re-drill to proper size</p>	<p>There is no written procedure regarding to repair/rework action.</p>	NC



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QUESTIONNAIRE	FINDINGS	SCORE
<p>Does the supplier perform maintenance on all production equipment (plants cleaning, lines, assembly stations, machines, production tools) and auxiliary equipment (electricity, compressed air, water) following a written maintenance program or checklist. Is the maintenance properly performed and recorded for equipment, tooling, etc. that directly affects product conformity. Are actions of routine or extra maintenance documented on a log sheet or equivalent document?</p> <ul style="list-style-type: none"> <li>- There shall be a programmed, preventive or predictive maintenance plan for all production equipment directly connected with the product (including machine tooling).</li> <li>- There shall be a programmed, preventive or predictive maintenance plan for auxiliary equipment (including machine tooling).</li> <li>- Every machine should be supplied with a checklist of required inspections and activities to be performed. This plan shall be complied with, and all interventions performed shall be recorded in a logbook (ordinary/extraordinary maintenance interventions included).</li> <li>- The records shall be analyzed to identify any weakness in the equipment and/or in the maintenance plan.</li> <li>- There shall be spare parts ready for those machines/tools that may cause stopping of production</li> <li>- Customer owned tooling, gages, etc, must be permanently identified and included in the maintenance plan.</li> <li>- When machinery, tooling, dies, etc. are not in use, there should be guidelines for their proper identification, storage and protection.</li> </ul>	<p>There is a written maintenance program, and the program is well implemented.</p>	<b>C</b>
<p>Are product and process quality trends monitored, updated and available for appropriate indicators (e.g. internal scrap, reworking, process capability, etc.)?</p> <p>Personnel shall be systematically informed about the quality progress of their own department through easily understandable charts or graphs relevant to the objectives and trends in product quality and process quality (type and number of non-conformities manufactured by their department, or work area).</p> <ul style="list-style-type: none"> <li>- Personnel shall be informed about the consequences related to non-conformances by means of bulletin boards, pictures, drawings, diagrams, and/or information meetings.</li> </ul>	<p>Yes, quality statistics of each worker group were on the blackboard, and all personnel can see it. See photo 24 for reference.</p>	<b>C</b>
<b>4 FINISHED PRODUCT - OUTGOING QUALITY</b>		
<p>Are periodic audits/inspections of finished product planned and performed?</p> <ul style="list-style-type: none"> <li>- The finished product must be inspected prior to release for shipment to ensure it meets all of the customers specifications.</li> <li>- Suppliers of wholegoods (complete products) shall conduct Customer Quality Audits (CQA) on the product.</li> </ul>	<p>Yes, the finished parts must be inspected before delivery.</p>	<b>C</b>
<p>Is the required inspection and test equipment available and suitable?</p>	<p>The inspection and test equipments are sufficient to quality control and they are in good condition. See photos 15, 16, 17, 18, 19 &amp; 20.</p>	<b>C</b>



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QUESTIONNAIRE	FINDINGS	SCORE
<ul style="list-style-type: none"> <li>- There shall be a sufficient quantity of inspection and test equipment to carry out the necessary controls (personal gages included).</li> <li>- Gages shall be of adequate measuring class commensurate to the requirements of drawings, regulations and importance of the features.</li> <li>- Gages maintenance/protection conditions shall be available at the work station.</li> <li>- Reference samples (template, master, etc) used to verify the operating condition of gages and inspection/test equipment (e.g. hardness tester, profilometer) shall be available, identified, maintained, and correctly stored.</li> <li>- Reference samples shall be used according to the frequencies set out in the control plans or per the manufacturers' recommendation.</li> <li>- Gage identification, calibration status and expiration date shall be ensured; e.g. calibration stickers on gages and test equipment.</li> <li>- The criteria adopted to guarantee the required controls during the gage calibration period shall be defined (in particular when the instrument is sent to external laboratories).</li> <li>- Storage and handling conditions, as-well-as maintenance of gages shall be defined.</li> </ul> <p>Note to Auditor: All gages MUST be included in the gage calibration program.</p>		C
<p>For each shipment, how is traceability assured between the product, processing documentation and inspection results?</p> <ul style="list-style-type: none"> <li>- There shall be a traceability link between the packaging label and the product and processing documents. This includes both internal and external processes; e.g. paint, plating, heat treat..</li> <li>- There shall be a system guaranteeing FIFO.</li> <li>- Lot traceability to the raw material and/or sub-supplier components shall be maintained when required by contract.</li> </ul>	<p>The castings can trace back to the test record by pouring date.</p>	C
<p>Is the product packaged according to the packaging specification; is it adequate to safeguard product quality up to its receipt by the customer; and are storage conditions adequate to safeguard and preserve product conformance (containers stacking, protection from atmospheric agents, temperature conditions, humidity, dust, steams, etc.)?</p>	<p>The finished parts are well packed.</p>	



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QUESTIONNAIRE	FINDINGS	SCORE
<ul style="list-style-type: none"> <li>- Packaging shall be appropriate to the type of product, transport method and customer's requirements.</li> <li>- All packings shall be positively identified in compliance with the internal procedure or the standards agreed to by the customer.</li> <li>- There shall be handling, packaging, storage, and delivery procedures in accordance with material flows in order to avoid any product mix.</li> <li>- Packaging shall be in a status of cleanliness commensurate to the type of product utilized; e.g. painted parts, hydraulic parts.</li> <li>- The procedure shall include the review of the products in the event that a packing shall break or fall.</li> <li>- Dangerous or perishable products shall be clearly identified and handled.</li> <li>- During unloading, staging, and storage operations, environmental conditions shall be such as to protect the integrity of the product and its packaging.</li> <li>- Bar code labels must meet the customer requirements.</li> <li>- The supplier shall ensure the bar codes are readable. (re-inspect with bar code scanner)</li> </ul>		C
<b>SECTION 5 - MANAGEMENT RESPONSIBILITY</b>		
<p>What is the supplier's program to train, qualify and set-up personnel, operators and inspectors?</p>	<p>There is a written training program, and the supplier can show training record.</p>	C
<p>How does the supplier measure the effectiveness of their training program?</p>	<p>The operators who have been trained must pass examination. The supplier can show the records of examination.</p>	C
<p>Further qualification shall take place after training to ensure the effectiveness of the program. Qualification criteria, with reference to controls/measures to be performed by the operator, shall be objective.</p>		C
<p>Does the supplier monitor on-time delivery to all customers, establish objectives, and develop improvement actions if the objective is not met?</p>	<p>No statistics or objectives of on-time delivery.</p>	NC
<p>The supplier must set objectives and monitor on-time delivery for all customers. Improvement actions must be developed if objectives are not met.</p>		NC
<p>Do non-conformances reported by customer's result in problem solving actions, and is the effectiveness monitored through the use of specific indicators?</p>	<p>There is a written program for corrective action, and the supplier can show the records.</p>	C



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QUESTIONNAIRE	FINDINGS	SCORE
<p>Rules for the management of non-conformities shall be defined/applied. They should include:</p> <ul style="list-style-type: none"> <li>- Analysis of non-conformity</li> <li>- Containment actions to prevent defects and suspected products are leaving the Supplier Plant</li> <li>- Root cause identification (including use of PFMEA, Cause and Effect Diagram, DOE, etc)</li> <li>- Final corrective actions</li> <li>- Verification of effectiveness</li> <li>- Extension of the improvement to similar process that may experience the same potential root cause</li> <li>- The results of the activities following the management of a non-conformity shall be used to improve control plans, the dock audits (operating modes, frequency, etc.) and to update the preventive analysis such as D/PFMEA.</li> <li>- Any data generated by the controls/claims shall be processed and aggregated to allow further analysis and investigation.</li> <li>- In the event of a customer complaint, written reports must be sent to the customer.</li> </ul>		C

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1. Factory Gate



2. Factory Building



3. Sample Parts



4. Sample Parts



5. Sample Parts



6. Machining Shop

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7. CNC Lathe



8. Heat Treat Furnace



9. Painting Area



10. Foundry View Outside



11. Arc Furnace



12. Automatic Molding Machine

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13. Core Making Machine



14. Raw Material (Pig Iron)



15. Chemical Analysis Machine



16. Metallographic Analysis



17. Tensile Test Machine



18. Hardness Tester

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XXXXXXXXXXXXXXXXXXXXXXXXXX

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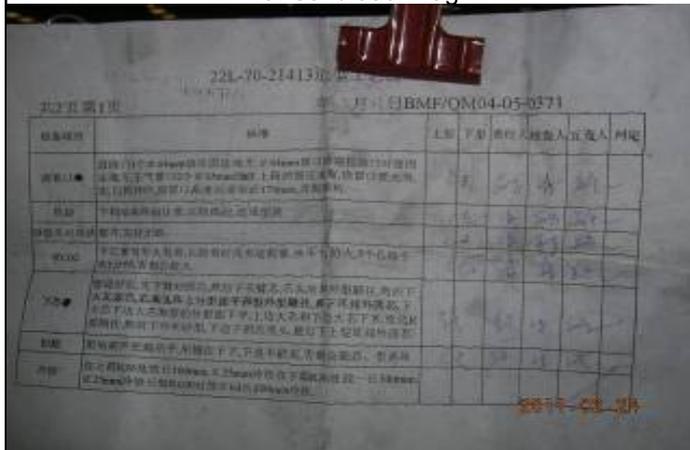
IEC00000372H



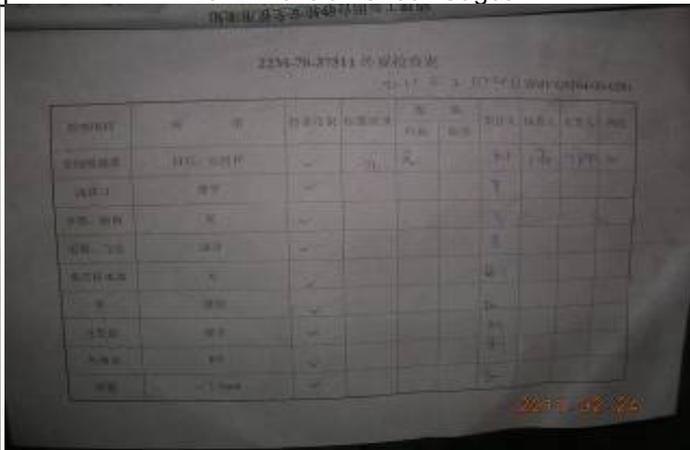
19. Calibration Tag



20. Dimension Check Gages



21. Working Instruction



22. Appearance Check Record



23. Dimension Check Record



24. Quality Statistics on Blackboard

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25. Packing



26. Non-conforming Parts



27. Test Record of Incoming Raw Material



28. MTC Format the Supplier Issued

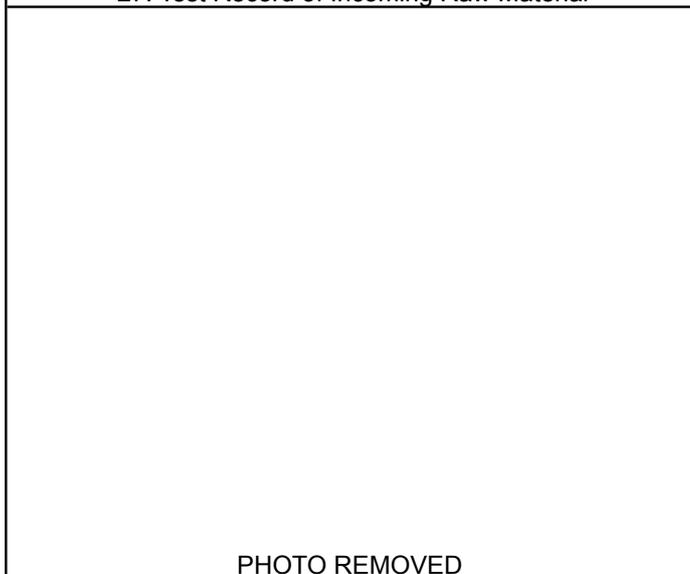
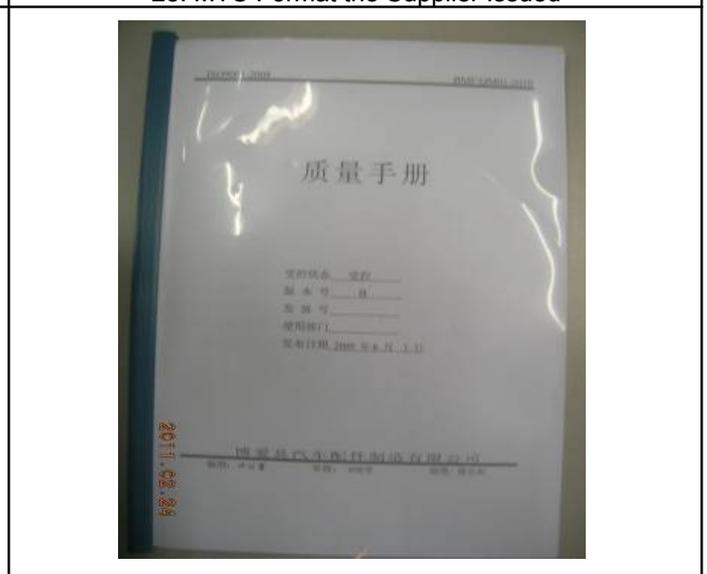


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29. ISO 9001 Certificate



30. Quality Manual