

**There are 22 case studies provided. Trainer would allot case studies to students for solving. Students should assess the audit findings. If it is a NC, student to write NC Report (Type of NC - Minor or Major, Standard Requirement and Reference Clause)**

1. During audit of Production process, Auditor reviews validation record for Welding processes. While auditing punching process on press machine no. M11 for Part "Washer" Auditor asks Auditee for validation record of punching process. Auditee replies that no validation carried out because it is not a special process.
2. While auditing Maintenance process, Auditee shows Preventive Maintenance plan and record for 500T Press machine no. P85. Out of 10 products, 7 products are being produced on P85 machine due to tonnage requirement. Auditor reviews record of Breakdown maintenance of P85 machine and observes that there are 3 incidents of Breakdown maintenance in a span of 2 months due to overheating of Motor. Total downtime due to Breakdown maintenance (3 incidents of Motor Over heating) is 33 hours and delivery rating in those 2 months is 70% and 60% due to production loss. Due to this Customer Score Card shows satisfaction level gone down to 70% from 90%. Auditor asks about predictive maintenance of press machine no. P85. Auditee replies that no such predictive maintenance carried out for machine no. P85
3. While auditing Marketing process, Auditor reviews Customer Satisfaction feedback survey record of Customer M/s. XYZ for year 2006-07. Customer satisfaction level is 97%. When Auditor reviews objective monitoring for marketing process he observes that in the month of March '07 there were 4 incidents of extra premium freights due to loss of production. Auditor ask for Customer satisfaction monitoring based on incidents of extra premium freight, but Auditee says our survey format do not have any point related to extra premium freight incidents.

4. While reviewing Feasibility Review record for Project no. 626, 632 and 643 for Customer M/s. XYZ, Auditee tells Auditor that there were 3 incidents of cancellation of Order by same Customer in last one year and company invested almost Rs. 1.50 crores for those particular projects. Also one of the existing products of above Customer requires plating and after quotation finalization Customer asked to have in-house plating plant. Customer refused to approve PPAP with plating process outsourced. Organization installed Plating shop and there were lot of issues related to waste management, storage of chemicals and employee health. Company suffered from heavy commercial loss due to that particular Customer. Auditor sees that risk analysis was not carried out during feasibility review of Project no. 626, 632 and 643.
5. While auditing H.R. process, Auditor observes that there is a major problem of Absenteeism. When Auditor sees the details, he observes that lot of contract people are working in assembly shop and 60% of those are not native. There was heavy absenteeism during Diwali period and Staff people had carried out assembly activities. There were cases of in-house rework but due to in time 100% Final Inspection no incident occurred regarding quality or delivery for that particular Customer. Auditor sees Contingency plan. He observes that no Contingency planning is being done for Labour problem.
6. While auditing Customer complaint handling process, Auditors reviews 8D report for complaint received from Customer M/s. XYZ for Part no. 123. 8D report is filled up for NC details, immediate actions, root cause analysis, CAPA and CAPA impact (Horizontal deployment). In CAPA details reference of review of Control Plan and PFMEA of Part no. 123 is evident and also details are evident in 8D report for training given to Production and QA team for Customer complaint and related CAPA. Auditor reviews Control Plan and PFMEA of Part no. 123 for necessary revisions and also interviews Final Inspector for awareness of CAPA. Auditors observes a statement in 8D report mentioning that same CAPA is being implemented for Part no. 456, 789 and 385. But Auditor observes that no revision carried out in Control Plan and PFMEA for Part no. 456, 789 and 385. Auditor checks complaint register and observes that there is no complaint for Part no. 456, 789 and 385.

7. During audit of Q.A. process Auditor observes that SPC study of dim. 11.00 mm of part "Bracket" is being carried out by Digital Vernier Caliper code no. VC-10 of L.C. 0.01 mm (0-150 mm). Cpk value is 0.9. When Auditor reviews Gauge R&R report of above Vernier Caliper %R&R is 44%. Gauge R&R study is being carried out after SPC study. As per Master List, VC-10 is being also used in Final Inspection and there were 2 complaints from Customer for dim. 11 mm of part "Bracket". Customer asks to carry out SPC (minimum Cpk of 1.67) for dim. 11.00 mm based on 2 complaints
8. While auditing receipt inspection process Auditor observes that castings for part "Base Plate" received from supplier ABC – 884 nos on 22/5/07 is being inspected, but all parameters mentioned in Control Plan are not checked. Out of 8 parameters only 5 were checked and record maintained. Auditors checks for in house rejection data and Customer complaint data. There is no incident of in house rejection and complaint for Part "Base Plate"
9. During audit of press shop, Auditor observes that Tool life monitoring of stamping tool no. T001 is not evident in Press Tool History Card for stamping process of Part "555" on Press M/c. no. 5 for production during period 27.12.06 to 31.12.06. Qty. produced during this period is 5,025 nos. Tool re sharpening frequency defined in Tool History Card is 1,000 nos. When Auditor asks Press shop supervisor, he replies that initially tool was checked after every 1,000 nos. and it was observed that tool condition remains good till production of 10,000 nos. So from last one year we are doing re sharpening after 10,000 nos. Only Tool History card is not revised to define tool re sharpening frequency as 10,000 by M.R. as he is responsible for any change in the system.

10. During audit of Final Inspection process auditor reviews Millipore test records for Finished product "Bearing". Millipore testing (To check cleanliness of product after ultrasonic washing process) is done for 5 parts in each lot of 100 parts as defined by Customer. Millipore value specified by Customer is 5 mg / part whereas actual observed Millipore value as per record of previous 10 lots is varying from 3 mg / part to 7 mg / part. Average of readings of 10 lots is 4.5 mg/ part. Auditor reviews the trend of Customer complaint and observes that there are total 4 complaints. Value observed at Customer end is above 10 mg / part in all the 4 cases. When Auditor sees Control Plan for Final Inspection there is a requirement of Clean Room whereas actual Final Inspection is being carried out in open area. When Auditor asks about Clean Room requirement, Auditee replies that NC was raised by Customer during their audit and Management have replied that within next 6 months they will install Clean Room. Auditor reviews Customer Audit Report and observes that Customer audit was conducted 8 months ago.
  
11. During audit of Maintenance process Auditors reviews Breakdown maintenance trend. Target given for year 2007 is 10 hours maximum per month. Auditor reviews the data and observes that 500 Ton press machine was under breakdown for 15 hours in the month of October '07. CNC Lathe was under breakdown for 25 hours in the month of November '07 and SPM was under breakdown for 30 hours in December '07. Total breakdown for year 2007 is 118 hours. Auditor asks for analysis of these 3 cases, Auditee replies that average actual breakdown per month is 9.83 hours against target of 10 hours per month. As target is being achieved no analysis done for the same.

12. While auditing Purchase process Auditor reviews Procedure for Supplier development. He observes that supplier development process covers: Initial visit to supplier - Updating Supplier Assessment Report – Supplier Audit (Minimum score require is 75%) – Compliance to ISO Certification by Supplier – P.O. to Supplier for PPAP – Supplier PPAP review – Supplier Approval – Approved Supplier Data base updating – Open P.O. and monthly schedule to supplier – Receipt inspection of every lot from supplier.

Auditor selects a supplier recommended by customer and asks auditee show the evidences as per defined procedure. Auditee replies that they do not follow procedure for customer recommended supplier because as customer is recommending these suppliers they are good suppliers.

13. On 28<sup>th</sup> February '08, during 2<sup>nd</sup> Surveillance audit of organization M/s. Perfect Industries, auditor audits QMS process. Auditor reviews procedure for Internal Audit and MRM. Frequency defined for internal audit is 3 months and followed by MRM. As per annual plan, internal audit was planned in March, June, September and December '07 and MRM was planned in April, July, October '07 and January '08. Auditor asks for records of internal audits and MRM carried out in the year 2007 from January '07 to December '07.

Auditee replies that March '07 Audit and April '07 MRM was not conducted because of year ending extra load. June '07 Audit and July '07 MRM was not conducted because MD, CEO and GM were abroad for business tour and M.R. was on leave for his marriage. Sept. '07 audit and Oct. '07 MRM was not conducted because there was heavy absenteeism. Dec. '07 audit and Jan. '08 MRM was not conducted because there was very less business.

Auditee shows Internal audit record and MRM record of Feb. '08 and says that they have covered review of complete year 2007. When auditor reviews NC summary of internal audit of Feb. '08 he observes total 48 NCs. In MRM record of Feb. '08 Auditor observes that there were orders for 120 parts from 6 different customers earlier. However, at present only 32 parts from only 1 customer are in the business basket. MD of that customer organization is a relative of CEO. There were total 22 complaints in a span of one year. There were 3 Customer Audits and the organization got Major NCs in all the 3 audits. When Auditor discusses the issue with CEO he replies that we will definitely improve our situation.

14. During complete audit of the organization Auditor observes that Customer Specific requirement of Customer M/s. Turbo Engineering are not being complied for PPAP submission, Cpk requirements, Internal Audit, MRM, Layout Inspection, Packing method, Customer Property handling and Pre despatch Inspection. There were NCs in Customer Audit for the same.
15. During audit of Enquiry handling process auditor observes that there is no evidence of review of statutory and regulatory requirements related to product and risk analysis in Contract Review check list dated 01.12.06 for enquiry received from Customer M/s. ABC for Part "Plate" Part no. 1234
16. During audit of Management Review process actual field failure received from customer Zenith Automotive is not covered by company ABC Auto Parts. When Auditor has asked about same to Auditee, he has replied that Management Review frequency defined in our Manual / Sec. QM: 5.6.1 is once in 6 months and we have carried out Management Review in last month and said field failure of Zenith Automotive is received just 4 days before. We are analysing the same and expecting the completion of it by next week maximum.
17. Company ABC has provided below basic information to the Auditor prior to coming to the audit.  
Location: Single – No remote sites  
Shifts running: 08:00-16:00 / 16:00-24:00 / 24:00-08:00  
No. of Employees: 20  
No. of Audit Days: 3.  
During Audit of Process called internal audit, auditee has shown the evidence of Internal Audit Plan and actual execution as per same. Auditor has observed that all the processes are covered during shifts 08:00 to 16:00 and 16:00 to 24:00. All NC closures are very well closed in effective way.

18. During of Audit of company Virat Automotive Suspensions Ltd., Auditor observed that Management is highly enthusiastic and innovative. When he asked Management to show the Process of Management Review. They have shown different levels and forums for Reviews. They are calling it MPCP and Level 1 / Level 2 / Level 3 documents with different frequencies. Level 1 frequency defined as once in a year / Level 2 frequency defined as once in six months and Level 3 frequency is once in 3 months. All frequencies are adhered effectively. However, agenda of overall Quality Objective reviews are not followed in all level reviews. When auditor has asked auditee for the same, he has replied that we are not following this agenda at all level, it is meant for Level 1 only. Subsequent levels are covering their process wise objectives as per defined frequencies effectively.
19. During audit of Process called MSA, Auditor has been shown the Attribute Study called Hypothesis Test for Measurement System: Digital Vernier for the Specification  $12.00 \pm 0.05$  mm referenced in Control Plan CP / 01 / Rev.01 by Laboratory-in-charge Mr. Mayur. Results are observed satisfactory. After completing check of audit sample, his Head Q.A., Mr. Shah has explained to the Auditor that, "Mr. Mayur is very experienced person among our team and seeing his loyalty to the company, Management has given him charge of Laboratory along with Stores."
20. During audit of process called "Grinding", auditor has observed that Instrument defined in Control Plan, CP/Grinding/01 Rev. 01 for the specification  $10 + 0.08$  mm is Micrometer. However, what was actually followed was Air Gauge. When Auditor asked about the same, auditee replied there is no risk to product since Air Gauge is much more advanced than Micrometer. Auditor has also verified and found no product / customer risk due to this.

21. During audit of company called ABC India for Process: Customer Complaint Handling, auditor came across one complaint of Line Stoppage at customer end. He has verified CAPA for the same which was found very systematic and presented to the customer with all the elements complete. Auditor has further reviewed and gone through the same.

Root causes identified are

1. Labor shortage,
2. Increased absenteeism due to Navaratri Festival, and
3. High Pressure Injection Moulding Line stopped due to Air Compressor failure and Service Provider could not be identified on time.

Auditor has been shown corrective action as:

"Management will look after such things personally and has taken serious note of such issues and guarantees not to repeat such situation again." Contingency planning was not evident with the organization.

22. During audit of company called Noel India, Auditor audited process called Customer Related Process. Auditor had taken note of Customer Specific Requirements (Doc. DML / Rev. 01) of customer Dipti Motors Ltd. regarding use of suppliers for their part development with List of Suppliers and the specific instruction "Do not use our competitor's supplier for new and confidential project development." After that auditor has gone for the audit of process called New Product Development. Auditor asked about PPAP activity of Part No. 1234 / Crankshaft for the customer Dipti Motors Ltd. Auditee has satisfactorily shown the all activities of PPAP to auditor with explanation to auditor that "This project is very prestigious for our company as well as for our customer too. So we have not taken any risk in development of same and decided to engage supplier Param Casting only, who is also topmost supplier to competitor of Dipti Motors. Casting part is key part of our product Crankshaft."