

Omnex Systems


3025 Boardwalk Suite 290, Ann Arbor, MI 48108

Internal QMS Platform

16 Nov 2021 - 16 Nov 2021

Lead Auditor **Anthony John**

Observer **User 05**

| Client Information | |
|------------------------|---|
| Company Name | Omnex Systems |
| Contact Person | User 05 |
| Department/Process | |
| Address | 3025 Boardwalk Suite 290, Ann Arbor, MI 48108 |
| Scope of Audit | |
| Dates of Audit | 16 Nov 2021 - 16 Nov 2021 |
| Location | 3025 Boardwalk Suite 290, Ann Arbor, MI 48108 |
| Type of Audit | Site Internal |
| Shift | SHIFT 9-6 |
| Lead Auditor Signature |  |

| Audit Plan | | | |
|------------|------|----------|-----------------------|
| Date | Time | Activity | Person(s) Interviewed |
| | | | |

| Audit Summary |
|---------------|
| |

| Positive Points |
|-----------------|
| |


| Opportunities for Improvement |
|-------------------------------|
| |

| Nonconformances | |
|------------------------------|--|
| Area/Process | Clause |
| | IATF 16949:2016 4.1 |
| Category: | Minor |
| Statement of nonconformance: | IATF 16949:2016 4.1->Understanding the organization and its context |
| Requirements: | IATF 16949:2016 4.1-The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization. |
| Objective Evidence: | IATF 16949:2016 4.1->Understanding the organization and its context |
| Procedure: | |









































































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|-------------|---|
| Attachment: | <u>~~~Audit speed Test~~.txt</u> <u>B&S15062020.xls</u> <u>2020 05 ~~~29 NXPs Attachment to Continental Inquiry to Power Seq Validation ~ F(00).txt</u> <u>APP 8000001 & %!@\$%^& TXN 7617603 TMPLT 228 (1) - Copy.pdf</u> |
|-------------|---|





















| Corrective Action (NCR) Summary - Issued | | | | | | |
|--|---------------------|---------|---|----------------------|-------------|---------------|
| CAR # | Standard Clause | Process | Details of Non-Conformance | Response Target Date | Date Closed | Date Verified |
| 2021-NOV-QA-IQP-AT-MA7SI-O2-4-411-NC-1 | IATF 16949:2016 4.1 | | IATF 16949:2016 4.1->Understanding the organization and its context | 11/20/2021 | | |





















| Conclusion |
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








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|-----------|--|------|------------|
| Signature |  NO IMAGES AVAILABLE | Date | 11-11-2021 |
|-----------|--|------|------------|


















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|-----------------|-----------|-------------------|
| Classification: | Category: | Retention Period: |
|-----------------|-----------|-------------------|




















| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|---|---|------|--|--|---------|---|
| 00. Painting Process | | | | | | |
|  |  | 01 | 01. Is SOP available at work station ? | 10   | |   |
|  |  | 02 | 02. Is Operator following the SOP during actual process ? | 6   | |   |
|  |  | 03 | 03. Confirm Paint colour is applid as per specification in SBM (Standard Bill of Material) | 6   | |   |
|  |  | 04 | 04. Check the painting process validation details. | 8   | |   |
|  |  | 05 | 05. Check add / change of washing solution & material lab Inspection frequency of Washing solution is used for Engine cleaning. | 8   | |   |
|  |  | 06 | 06. Check as per work instruction, degreasing temperature maintained or not | 2   | |   |
|  |  | 07 | 07. Check & verify preventive maintainence of Washing booth, Paint Kitchen, Paint booth, paint booth panel etc., | 10   | |   |
|  |  | 08 | 08. Check & verify Calibration of DFT meter, Gloss meter, Viscosity Cup. | 10   | |   |
|  |  | 09 | 09. Check & verify whether, after engine washing traces of water outside tappet cover housing & other areas etc. | 4   | |   |
|  |  | 10 | 10. Check & verify Masking is done at specified area as given in work instruction. | 10   | |   |
|  |  | 11 | 11. Check & verify, Viscosity measurements of paint & cross verified with work instrcution for specification, also check the records for the same. | 4   | |   |
|  |  | 12 | 12. Check air pressure required for Painting, Pressure gauge calibration. | 6   | |   |

















| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|-------------------------------------|--------------------------|------|--|-----------------------------------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 13 | 13. Check Painting nozzle cleanliness & maintainence. | 10 <input type="text" value="v"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 14 | 14. Confirm expiry dates on paint tin. | 10 <input type="text" value="v"/> | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 15 | 15. Check & verify as per standard or WI, spray paint on engine as per specified distance. | 8 <input type="text" value="v"/> | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 16 | 16. Ensure Cleanliness of all storage solution tanks. | 8 <input type="text" value="v"/> | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 17 | 17. Check DFT (Dry Film Thickness) measurements on engine using DFT meter & cross verify with work instrcution specification, also check the records for the same. | 8 <input type="text" value="v"/> | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 18 | 18. Check Gloss measurements on engine using gloss meter & cross verify with work instruction specification, also check the records for the same. | 8 <input type="text" value="v"/> | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 19 | 19. Check & verify paint shade on engine. | 8 <input type="text" value="v"/> | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 20 | 20. Check Adhesion test on engine & cross verified with NEBS specification, also check the records for the same. (Ref. Work Instruction) | 6 <input type="text" value="v"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 21 | 21. Is the operator trained to do the job at work station ? | 10 <input type="text" value="v"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 22 | 22. Is Skill matrix available for operator for the job he is doing | 10 <input type="text" value="v"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 23 | 23. Check & verify whether, all Information captured in work instruction are as per Enginnering standard. | 10 <input type="text" value="v"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 24 | 24. Cross verify the work instruction revision no with QSI or EASE system to confirm mismatcheds if any. | 10 <input type="text" value="v"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 25 | 25. If Engineering Standard available, then Check revision in PLM & refer it for referance. | 10 <input type="text" value="v"/> | |  |
| 01. Millipore Process | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 01 | 01.Is SOP available at work station ? | B | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 02 | 02. Is Operator following the SOP in the actual process ? | A | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 03 | 03. Check solution used for millipore cleanliness level for its checking frequency & records for the same. | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 04 | 04. Check millipore brush sizes, brush changing frequency & brush storage condition. | B | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 05 | 05. Check proper routine of millipore mobile trolley for drain system (bend). | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 06 | 06. As per WI, Check Oven temperature to maintain within specification. | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 07 | 07. Check as per WI, vacuum pressure within specification. | | |  |




















































| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--------------------------|--------------------------|------|---|--------------------------------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 08 | 08. Check & Verify the calibration of Vacuum guage, Magnification lens, Millipore oven etc. | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 09 | 09. Check millipore lab codition such as ventilation in lab, exhaust fan condition. | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 10 | 10. Check & Verify measurement of particle weight as per specification in WI / Engg. Std | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 11 | 11. Check & Verify measurement of Overall weight as per specification in WI. | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 12 | 12. Is Skill matrix available for operator ? | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 13 | 13. Verify whether all Information captured in work instruction as per Enginnering standard. | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 14 | 14. Cofirm the work instruction revision no with QSI or EASE system. For ex. WI: A24760 MIW parts WI: A24766 | | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 15 | 15. If Engineering Standard available, then Check revision in PLM & refer it for referance. Engg. Std. 16233, 16724 | | |  |
| 02. Camshaft Rumbling | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 01 | 01. Is SOP available at work station ? | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 02 | 02. Is Operator following the SOP in the actual process ? | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 03 | 03. Check condition / unique number if any, of tackles used to lift the camshaft. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 04 | 04. Check rumbling stone change / add frequency, inspection frequency as per WI & records for the same. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 05 | 05. Check & verify stone level in machine for rumbling operation as per WI. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 06 | 06. Check rumbling solution fill quantity as per work instruction & records for the same. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 07 | 07. Check & Verify Control or monitoring to ensure camshaft has undergone the required cycle time for rumbling. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 08 | 08. Check & Verify machine vibration/amplitude level on amplitude graph as per WI & Ensure condition of graph. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 09 | 09. Check camshaft storage condition after rumbling. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 10 | 10. Check maintainence of rumbling machine & condition of machine. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 11 | 11. Check & Verify as per WI surface finish measurement within specification. | <input type="text" value="0"/> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 12 | 12. Is Skill matrix available for operator ? | <input type="text" value="0"/> | |  |




















| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|--------------------------|------|--|----------------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 13 | 13. All Information captured in work instruction as per Enginnering standard. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 14 | 14. Cofirm the work instruction revision no with QSI or EASE system. WI: A22319 | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 15 | 15. If Engineering Standard available, then Check revision in PLM & refer it for referance. Engg. Std. 18258, 18282 | <div>0</div> | |  |
| 03. Camshaft Induction Hardening | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 01 | 01. Is SOP available at work station ? | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 02 | 02. Is Operator following the SOP in the actual process ? | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 03 | 03. Check camshaft are fitted with alignment in jaws in hardening machine & keep specified disatnce between heating coil & camshaft. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 04 | 04. Verify Sight glass of hardening machine is clean. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 05 | 05. Check quenching pressure & coolant temaperature within specification as per work instruction. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 06 | 06. Check & Verify calibration of pressure gauges & temperature gauges. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 07 | 07. Check tempering temperature within specification as per work instruction. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 08 | 08. Check PM of hardening machines & tempring furnace. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 09 | 09. Check over all conddition of machine. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 10 | 10. Check induction hardening pattern & case depth as per WI given in respective drawing & records for the same. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 11 | 11. Check baking records for water cooling coil. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 12 | 12. Is Skill matrix available for operator ? | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 13 | 13. All Information captured in work instruction as per Enginnering standard. | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 14 | 14. Cofirm the work instruction revision no with QSI or EASE system. A34350, A23578, A24025 | <div>0</div> | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 15 | 15. If Engineering Standard available, then Check revision in PLM & refer it for referance. | <div>0</div> | |  |
| 4.1 Understanding the organization and its context | | | | | | |
|  | <input type="checkbox"/> | 1.0 | How has the organization determined external and internal issues relevant to its purpose and strategic direction? | <div>N/E</div> | |  |
|  | <input type="checkbox"/> | 1.1 | How do these affect the ability to achieve the intended result of the QMS? | <div>N/E</div> | |  |

















| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|--------------------------|------|--|-------|---------|---|
| ✓ | <input type="checkbox"/> | 1.2 | How do you monitor and review information about these internal and external issues? | N/E | |  |
| 5.2 Quality policy | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.16 | How does top management establish, review and maintain a quality policy? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.17 | How is it determined to be appropriate to the purpose and context of the organization? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.18 | Does it provide a framework for setting and reviewing quality objectives? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.19 | Does it contain a commitment to satisfy applicable requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.20 | Does it include a commitment to continual improvement of the QMS? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.21 | Where is the quality policy available as documented information? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.22 | How is it communicated? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.23 | Show me how it is understood and applied within the organization. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.24 | How have you made it available to relevant interested parties? | N/E | |  |
| 5.3 Organizational roles, responsibility and authorities | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.25 | How does top management ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.26 | How does top management assign the responsibility and authority for: Ensuring that the QMS conforms to the International standard? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.27 | Ensuring processes are delivering their intended outputs? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.28 | How is the performance of the QMS, opportunities for improvement and the need for change or innovation reported to top management? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.29 | How is customer focus promoted within the organization? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.30 | How is the integrity of the QMS maintained when changes to the QMS are planned and implemented? | N/E | |  |
| 6.1 Actions to address risks and opportunities | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.0 | How are the internal and external issues and interested parties considered when planning for the QMS? | N/E | |  |















| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|---|--------------------------|------|--|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 3.1 | How are risks and opportunities determined and addressed so that the QMS can: a) achieve its intended results; b) Prevent or reduce undesired effects; c) Achieve continual improvement? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.2 | How are actions planned to address risks and opportunities? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.3 | How are actions integrated and implemented into the QMS processes? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.4 | How do you evaluate the effectiveness of the actions? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.5 | How are actions taken to address risks and opportunities determined as being appropriate to the potential impact on the conformity of products and services? | N/E | |  |
| 6.2 Quality objectives and planning to achieve them | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.9 | Where are the quality objectives and are these at all relevant functions, levels and processes? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.10 | Are they consistent with the quality policy? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.11 | Are they measurable? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.12 | Do they consider applicable requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.13 | Are they relevant to the conformity of products and services and do they enhance customer satisfaction? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.14 | Are they monitored? How? How often? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.15 | How are they communicated? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.16 | How are they updated? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.17 | Where is the documented information on the quality objectives? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.18 | How does the organization determine what will be done, with what resources, when completed and how will results be evaluated for quality objectives? | N/E | |  |
| 6.2.2.1 Product design skills | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.6 | How do you determine that personnel with product design responsibility are competent to achieve design requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.7 | How do you determine skills required in applicable tools and techniques? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.8 | How do you identify applicable tools and techniques? | N/E | |  |
| 6.3 Planning of changes | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.19 | How are changes to the QMS planned systematically? | N/E | |  |

| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|--------------------------|------|---|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 3.20 | Demonstrate the purpose and potential consequences of changes | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.21 | Demonstrate the integrity of the QMS | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.22 | Demonstrate how resources are made available? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3.23 | Demonstrate how responsibility and authority is allocated or reallocated. | N/E | |  |
| 7.0 Support | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.0 | Demonstrate how resources are determined for the establishment, implementation, maintenance and continual improvement of the QMS. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.1 | Show me how the capabilities and constraints on internal resources are considered. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.2 | Show me how needs from external providers are considered. | N/E | |  |
| 7.1.2 People | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.3 | How do you provide persons necessary to consistently meet customer, applicable statutory and regulatory requirements for the QMS including the necessary processes? | N/E | |  |
| 7.1.5 Monitoring and measuring resources | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.6 | How are the resources determined for ensuring valid and reliable monitoring and measuring results, where used? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.7 | How do you ensure that resources provided are suitable for the specific monitoring and measurement activities and are maintained to ensure continued fitness for purpose? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.8 | Show me the documented information which is evidence of fitness for purpose of monitoring and measurement resources. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.9 | Where applicable, show me how measurement instruments are: Verified or calibrated at specified intervals against national or international measurement standards | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.10 | If there are no standards, show me the documented information which is used as the basis used for calibration or verification. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.11 | Show me how measurement instruments are identified to determine their calibration status. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.12 | Show me how they are safeguarded from adjustments. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.13 | Show me how they are safeguarded from damage and deterioration. | N/E | |  |















| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|---|------|--|-------|---------|---|
|  |  | 4.14 | How do you determine the validity of previous measurements if you find an instrument to be defective during verification or calibration? | N/E | |  |
|  |  | 4.15 | What appropriate actions can you take? | N/E | |  |
| 7.1.3 Infrastructure | | | | | | |
|  |  | 4.4 | How do you determine, provide and maintain the infrastructure for the operation of processes to achieve products and service conformity? | N/E | |  |
| 7.1.4 Environment for the operation of processes | | | | | | |
|  |  | 4.5 | How do you determine, provide and maintain the environment for the operation of processes to achieve products and service conformity? | N/E | |  |
| 7.1.6 Organizational knowledge | | | | | | |
|  |  | 4.16 | How do you determine necessary knowledge for the operation of processes? | N/E | |  |
|  |  | 4.17 | How do you determine necessary knowledge to achieve conformity of products and services? | N/E | |  |
|  |  | 4.18 | How do you maintain this knowledge and how do you make it available to the extent necessary? | N/E | |  |
|  |  | 4.19 | How do you consider current knowledge and how do you acquire additional knowledge when addressing changing needs and trends? | N/E | |  |
| 7.2 Competence | | | | | | |
|  |  | 4.20 | Show me how: You determine the necessary competence of people doing work under your control that affects quality performance | N/E | |  |
|  |  | 4.21 | How do you determine competence on the basis of appropriate education, training or experience? | N/E | |  |
|  |  | 4.22 | How do you take actions to acquire necessary competence where applicable and how do you evaluate the effectiveness of those actions? | N/E | |  |
|  |  | 4.23 | Show me documented information where appropriate of competence. | N/E | |  |
| 7.3 Awareness | | | | | | |
|  |  | 4.24 | How are people aware of the quality policy? | N/E | |  |
|  |  | 4.25 | How are people aware of relevant quality objectives? | N/E | |  |
|  |  | 4.26 | Their contribution to the effectiveness of the QMS? | N/E | |  |
|  |  | 4.27 | The benefits of improved performance? | N/E | |  |
|  |  | 4.28 | The implications of not conforming with the QMS requirements? | N/E | |  |
| 7.4 Communication | | | | | | |














| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|---|--------------------------|------|--|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 4.29 | How do you determine internal and external communications relevant to the QMS? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.30 | How do you determine: What? When? With Whom? How? | N/E | |  |
| 7.5 Documented information | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.31 | What documented information do you have as required by this standard? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.32 | What documented information do you have as being necessary for the effectiveness of your QMS? | N/E | |  |
| 7.5.2 Creating and updating | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.33 | Show me that your documented information contains: Identification and Description. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.34 | In what media format is your documented information? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.35 | Show me how the documented information is reviewed and approved for suitability and adequacy. | N/E | |  |
| 8.1 Operational planning and control | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.0 | How are processes needed to meet requirements for provision of products and services planned, implemented and controlled? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.1 | How are requirements for products and services determined? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.2 | How is criteria for processes and acceptance for products and services determined? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.3 | How are resources determined? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.4 | How is process control implemented? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.5 | Show me the documented information that shows confidence in that the processes have been carried out as planned and can demonstrate conformity of products and services. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.6 | How have you determined that the output from the planning process is suitable for your operations? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.7 | How do you control planned changes? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.8 | How do you review the consequences of unintended changes? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.9 | What action is taken to mitigate any adverse effects? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.10 | How do you control outsourced processes? | N/E | |  |
| 7.5.3 Control of documented information | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.36 | Show me how you control documented information. | N/E | |  |

| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|--------------------------|------|--|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 4.37 | Show me how you make it available and suitable for use. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.38 | How do you protect your documented information? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.39 | When controlling documented information, how do you address: Distribution; Access; Retrieval; Use; Storage and preservation; Legibility; Control of changes; Retention and disposition. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4.40 | How do you identify as appropriate and control documented information of external origin which you have determined as necessary for the QMS | N/E | |  |
| 8.2.2 Determination of requirements related to products and services | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.13 | What is your process to determine the requirements for products and services to be offered to potential customers? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.14 | How do you establish, implement and maintain this process? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.15 | How do you define product and service requirements including statutory and regulatory requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.16 | How do you ensure that you have the ability to meet the defined requirements and substantiate any claims for your products and services? | N/E | |  |
| 8.2.3 Review of requirements related to products and services | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.17 | How do you review customer requirements for delivery and post-delivery? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.18 | How do you review requirements necessary for customers' specified or intended use, where known? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.19 | How do you review additional statutory and regulatory requirements applicable to products and services; | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.20 | How do you review any other contract or order requirements. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.21 | Show me that the review is conducted prior to your commitment to supply products and services to your customers | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.22 | How do you resolve contract or order requirements which differ from those previously defined? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.23 | How do you confirm customer requirements where the customer does not provide a documented statement? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.24 | Show me where you retain documented information which describes results of the review including any new or changed requirements. | N/E | |  |















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|---|--------------------------|------|--|-------|---------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 5.25 | Show me the documented information containing changes to products and services. How do you ensure that relevant personnel are made aware of those changes? | N/E | |  <input type="checkbox"/> |
| 8.2.1 Customer communication | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.11 | What are your processes for communicating with customers? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.12 | How do you communicate information relating to: Products; Services; Enquiries; Contracts; Order handling; Customer views, perceptions and complaints; Handling or treatment of customer property; Specific requirements for contingency actions? | N/E | |  <input type="checkbox"/> |
| 8.3 Design and development of products and services | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.26 | How do you establish, implement and maintain a design and development process (where detailed requirements of your products and services are not already established or defined by the customer or other parties)? | N/E | |  <input type="checkbox"/> |
| 8.3.2 Design and development planning | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.27 | When determining the stages and control for design and development, show me how you consider:The nature, duration and complexity of the activities; Requirements that specify particular process stages including applicable reviews; Required verification and validation;Responsibilities and authorities. | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.28 | How are interfaces are controlled between individuals and parties involved in the design and development process? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.29 | How is the need for involvement of customer and user groups considered? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.30 | Show me documented information that confirms design and development requirements have been met. | N/E | |  <input type="checkbox"/> |
| 8.3.3 Design and development inputs | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.31 | Show me how you determine Functional & performance requirements | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.32 | Show me how you determine what Statutory and regulatory requirements are applicable | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.33 | Show me how you determine Standards or codes of practice where there is a commitment to implement | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.34 | Show me how you determine Internal and external resources needed for the design and development of products and services | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.35 | Show me how you determine potential consequences of failure | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.36 | Show me how you determine the level of control expected of the design and development process by customers and other relevant parties. | N/E | |  <input type="checkbox"/> |





































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|--|--------------------------|------|---|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 5.37 | How do you determine that inputs are adequate, complete and unambiguous for design and development? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.38 | How do you resolve conflicts among inputs? | N/E | |  |
| 8.3.4 Design and development controls | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.39 | How do controls that are applied to the design and development process ensure results achieved by design and development activities are clearly defined? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.40 | How do controls ensure Design and development reviews are conducted as planned? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.41 | How do controls ensure outputs meet the input requirements by verification? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.42 | How do controls ensure validation is conducted to ensure that the resulting products and services are capable of meeting the requirements for the specified application or intended use (when known)? | N/E | |  |
| 8.3.5 Design and development outputs | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.43 | How do you ensure that design and development outputs meet the input requirements for design and development? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.44 | How are D & D outputs ensured adequate for the subsequent processes for the provision of products and services? Include or reference monitoring and measuring requirements, and acceptance criteria, as applicable? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.45 | How do D & D outputs ensure products to be produced, or services to be provided, are fit for intended purpose and their safe and proper use? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.46 | Show me the documented information which results from the design and development process. | N/E | |  |
| 8.3.6 Design and development changes | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.47 | How do you review, control and identify changes made to the design inputs and outputs during design and development of products and services ensuring no impact on conformity to requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.48 | Show me the documented information for design and development changes | N/E | |  |
| 8.4.2 Type and extent of control of external provision | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.56 | How do you determine the controls applied to the external provision of processes, products and services and take into consideration: the potential impact of the externally provided processes, products and services on the ability to consistently meet customer and applicable statutory and regulatory requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.57 | What controls are considered for the perceived effectiveness of the controls applied by the external provider? | N/E | |  |












































































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|---|--------------------------|------|--|-------|---------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 5.58 | What verification or other activities do you have to ensure externally provided processes, products and services do not adversely affect your ability to consistently deliver conforming products and services to your customers? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.59 | When processes or functions have been outsourced to external providers, how do you consider a) and b) in 8.4.1 and how do you define the controls intended to be applied to the external provider and to the resulting process output? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.60 | Show me how you communicate to external providers, applicable requirements for Products and services to be provided or the processes to be performed on behalf of the organization. | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.61 | Show me how you communicate to external providers, applicable requirements for Approval or release of products and services, methods, processes or equipment | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.62 | Show me how you communicate to external providers, applicable requirements for competence of personnel, including necessary qualification | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.63 | Show me how you communicate to external providers, applicable requirements for their interactions with Raymond's quality management system | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.64 | Show me how you communicate to external providers, applicable requirements for the control and monitoring of the external provider's performance to be applied by Raymond | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.65 | Show me how you communicate to external providers, applicable requirements for verification activities that the organization, or its customer, intends to perform at the external provider's premises. | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.66 | Before you communicate with external providers, how do you ensure the adequacy of specified requirements? | N/E | |  <input type="checkbox"/> |
| 8.5.1 Control of production and service provision | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.67 | What controlled conditions do you have for production and service provision, including delivery and post-delivery activities? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.68 | Show me the availability of documented information defining the characteristics of the products produced, services provided, and results to be achieved. | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.69 | Show me controlled conditions for the availability of documented information defining the activities to be performed and the results to be achieved. | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.70 | Show me the availability and use of suitable monitoring and measurement resources | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.71 | Show me monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met. | N/E | |  <input type="checkbox"/> |
















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|--|--------------------------|------|--|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 5.72 | Show the use, and control of suitable infrastructure and process environment | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.73 | Demonstrate the competence and, where applicable, required qualification of persons | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.74 | Demonstrate the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.75 | Show the implementation of products and services release, delivery and post-delivery activities. | N/E | |  |
| 8.4 Control of externally provided products and services | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.49 | How do you ensure externally provided processes, products and services conform to specified requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.50 | Show me how you apply specified requirements for the control of externally provided products and services when Products and services are provided by external providers for incorporation into your own products and services. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.51 | Show me how you apply specified requirements for the control of externally provided products and services when products and services are provided directly to customers by external providers on your behalf. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.52 | Show me how you apply specified requirements for the control of externally provided products and services when a process or part-process is provided by an external provider as a result of a decision to outsource a process or function. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.53 | Show me how you establish and apply criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.54 | How do you assess their ability to provide processes or products and services in accordance with specified requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.55 | What documented information do you have of the results of evaluations, monitoring of performance and re-evaluations of external providers? | N/E | |  |
| 8.5.2 Identification and traceability | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.76 | What means do you use to identify process outputs to ensure conformity of products and services? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.77 | How do you identify the status of process outputs? | N/E | |  |

















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|--|------------------------|------|---|-------|---------|------------------------|
| <div><div></div></div> | <div><div></div></div> | 5.78 | How do you control the unique identification of process outputs, where applicable? What documented information do you retain? | N/E | | <div><div></div></div> |
| 8.5.3 Property belonging to customers or external providers | | | | | | |
| <div><div></div></div> | <div><div></div></div> | 5.79 | What care do you provide for customer or external provider’s property while under your control? | N/E | | <div><div></div></div> |
| <div><div></div></div> | <div><div></div></div> | 5.80 | How do you identify, verify, protect and safeguard that property which is provided for use or incorporation into your products or services? | N/E | | <div><div></div></div> |
| <div><div></div></div> | <div><div></div></div> | 5.81 | What means do you use to report to the customer or external provider if their property is incorrectly used, lost, damaged or found to be unsuitable for use? | N/E | | <div><div></div></div> |
| 8.5.4 Preservation | | | | | | |
| <div><div></div></div> | <div><div></div></div> | 5.82 | How do you ensure preservation of process outputs during production and service provision to maintain conformity to product requirements? NOTE Preservation can include identification, handling, packaging, storage, transmission or transportation, and protection. | N/E | | <div><div></div></div> |
| 8.5.5 Post-delivery activities | | | | | | |
| <div><div></div></div> | <div><div></div></div> | 5.83 | How do you meet requirements for post-delivery activities associated with products and services? | N/E | | <div><div></div></div> |
| <div><div></div></div> | <div><div></div></div> | 5.84 | How do you determine: Risk; Nature, use and intended lifetime; Customer feedback;Statutory and Regulatory requirements, when determining the extent of post-delivery activities required with products and services? NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal. | N/E | | <div><div></div></div> |
| 8.5.6 Control of changes | | | | | | |
| <div><div></div></div> | <div><div></div></div> | 5.85 | How do you review and control unplanned changes to ensure continuing conformity with specified requirements? | N/E | | <div><div></div></div> |
| <div><div></div></div> | <div><div></div></div> | 5.86 | What documented information can you show me which describes the results of reviews of changes, the personnel authorizing change and any necessary actions? | N/E | | <div><div></div></div> |
| 8.6 Release of products and services | | | | | | |
| <div><div></div></div> | <div><div></div></div> | 5.87 | Show me how planned arrangement have been implemented at appropriate stages to verify product and service requirements have been met. Show me what evidence you retain. | N/E | | <div><div></div></div> |
| <div><div></div></div> | <div><div></div></div> | 5.88 | Show me how the release of products and services is held until planned arrangements for verification of conformity have been satisfactorily completed, unless approved by a relevant authority, or the customer if applicable. | N/E | | <div><div></div></div> |
| <div><div></div></div> | <div><div></div></div> | 5.89 | Show me documented information which shows traceability to the person authorizing release of products and services. | N/E | | <div><div></div></div> |
| 8.7 Control of non-conforming process outputs, products and services | | | | | | |




















| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|--------------------------|------|---|-------|---------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 5.90 | How do you identify and control process outputs, products and services that do not conform to requirements and prevent their unintended use or delivery? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.91 | What appropriate corrective actions are taken based on the nature of the nonconformity and its impact on the conformity of products and services? How do you apply this to nonconformity detected after delivery? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.92 | How you deal with nonconforming process outputs, products and services in terms of:Correction? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.93 | How you deal with nonconforming process outputs, products and services in terms of Segregation, containment, return or suspension of provision of products and services? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.94 | How you deal with nonconforming process outputs, products and services in terms of Informing the customer? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.95 | How you deal with nonconforming process outputs, products and services in terms of Obtaining authorization for use as-is? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.96 | How you deal with nonconforming process outputs, products and services in terms of Release, continuation or re-provision of the products and service? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.97 | How you deal with nonconforming process outputs, products and services in terms of Acceptance under concession? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.98 | How do you verify conformance where process outputs, products and services are corrected following nonconformance? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 5.99 | What documented information do you keep following actions taken to address nonconformities, including any concessions obtained and on the person or authority that made the decision regarding dealing with the nonconformance. | N/E | |  <input type="checkbox"/> |
| 9.1 Monitoring, measurement, analysis and evaluation | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.0 | Show me how you determine what needs to be monitored and measured? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.1 | Show me how you determine methods for monitoring, measurement, analysis and evaluation to ensure valid results? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.2 | Show me how you determine when to perform monitoring and measuring? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.3 | Show me how you determine when results shall be analysed and evaluated? | N/E | |  <input type="checkbox"/> |

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|-------------------------------|--------------------------|------|--|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 6.4 | What documented information can you show me that monitoring and measurement activities have been implemented in accordance with determined requirements? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.5 | Show me how you evaluate the quality performance and the effectiveness of the QMS. | N/E | |   |
| 9.1.3 Analysis and evaluation | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.9 | Show me how you analyse and evaluate data and information arising from monitoring, measurement and other sources. | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.10 | Show me how the output of analysis and evaluation is used to demonstrate conformity of products and services to requirements? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.11 | Show me how the output of analysis and evaluation is used to assess and enhance customer satisfaction. | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.12 | Show me how the output of analysis and evaluation is used to ensure conformity and effectiveness of the QMS | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.13 | Show me how the output of analysis and evaluation is used to demonstrate that planning has been successfully implemented | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.14 | Show me how the output of analysis and evaluation is used to assess process performance | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.15 | Show me how the output of analysis and evaluation is used to assess performance of external providers | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.16 | Show me how the output of analysis and evaluation is used to determine the need or opportunities for improvements within the QMS | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.17 | Show me where the results of analysis and evaluation are used to provide inputs to management review. | N/E | |   |
| 9.3 Management Review | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.27 | What is the frequency that top management reviews the organization's QMS? How is the QMS deemed suitable, adequate and effective? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.28 | Are action status of previous reviews reviewed? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.29 | Are changes to internal/external issues relevant to the QMS reviewed? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.30 | Are issues that affect strategy reviewed? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.31 | Are KPIs for nonconformities and corrective actions reviewed? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.32 | Are monitor and measurement of results reviewed? | N/E | |   |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.33 | Are audit results reviewed? | N/E | |   |

| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|---|---|------|--|-------|---------|---|
|  |  | 6.34 | Is customer satisfaction reviewed? | N/E | |   |
|  |  | 6.35 | Are issues concerning external providers reviewed? | N/E | |   |
|  |  | 6.36 | Are issues concerning other relevant parties reviewed? | N/E | |   |
|  |  | 6.37 | Are adequacy of resources and effectiveness of QMS reviewed? | N/E | |   |
|  |  | 6.38 | Is process performance reviewed? | N/E | |   |
| |  | 6.39 | Are conformity of products and services reviewed? | N/E | |   |
|  |  | 6.40 | Are actions taken to address risks and opportunities and their effectiveness reviewed? | N/E | |   |
|  |  | 6.41 | Are new potential opportunities for continual improvement reviewed? | N/E | |   |
|  |  | 6.42 | Show me that management reviews include decisions and actions relating to: Continual improvement opportunities; the need for changes to the QMS including resource needs. | N/E | |   |
|  |  | 6.43 | Show me what documented information you have as evidence of management reviews. | N/E | |   |
| 9.2 Internal audit | | | | | | |
|  |  | 6.18 | Are internal audits being conducted at planned intervals? | N/E | |   |
|  |  | 6.19 | Do they determine whether the QMS conforms to the requirements of ISO 9001 and to the other requirements established by Raymond? (Review records to demonstrate conformance) | N/E | |   |
|  |  | 6.20 | Do they determine whether the QMS is effectively implemented and maintained? (Review records) | N/E | |   |
|  |  | 6.21 | Does the audit program take into consideration the quality objectives, importance of the processes, customer feedback, changes impacting the Raymond and the results of previous audits? | N/E | |   |
|  |  | 6.22 | Where are the audit criteria and scope for each audit? | N/E | |   |
|  |  | 6.23 | Can you demonstrate that selection of auditors and the conduct of audits are objective and impartial and that auditors don't audit their own work? | N/E | |   |
|  |  | 6.24 | How are audit results reported to relevant management? | N/E | |   |
|  |  | 6.25 | Can you demonstrate that necessary correction and corrective actions are taken without undue delay? | N/E | |   |
|  |  | 6.26 | Show me documented information of the audit program and the audit results. | N/E | |   |
| 9.1.2 Customer satisfaction | | | | | | |

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|--|--------------------------|------|--|-------|---------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 6.6 | How do you monitor customer perception of the degree to which requirements have been met? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.7 | How do you obtain information relating to customer views and opinions of your products and services? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 6.8 | What methods for obtaining and using this information do you have? | N/E | |  <input type="checkbox"/> |
| 10.1 General | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.0 | How do you determine and select opportunities for improvement? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.1 | What necessary actions have you implemented so that you have met customer requirements and enhanced customer satisfaction? | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.2 | Show me how you have: Improved processes to prevent nonconformities; Improved products and services to meet known and predicted requirements; Improved QMS results. | N/E | |  <input type="checkbox"/> |
| 10.2 Nonconformity and corrective action | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.3 | Show me how you react to a nonconformity: take action to control and correct it or deal with the consequences | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.4 | Show how you take action to control and correct it | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.5 | Show how you evaluate the need for action to eliminate the cause so that it does not recur or occur elsewhere by: Reviewing the nonconformity; Determining the cause of the nonconformity; Determining if similar nonconformities exist or could potentially occur | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.6 | Show actions needed are implemented | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.7 | Show how you review the effectiveness of corrective actions taken, if any | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.8 | Show if necessary changes to the QMS were implemented | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.9 | Show me how correction actions were appropriate to the effects of the nonconformities encountered. | N/E | |  <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.10 | What documented information can you show me as evidence of: The nature of the nonconformities and subsequent actions taken?; The results of any corrective action? | N/E | |  <input type="checkbox"/> |
| 10.3 Continual improvement | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.11 | Demonstrate that you continually improve the suitability, adequacy and effectiveness of the QMS. | N/E | |  <input type="checkbox"/> |

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|---|--------------------------|------|---|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 7.12 | Demonstrate that outputs of analysis and evaluation and the outputs from management review are considered to confirm if there are areas of underperformance or opportunities that shall be addressed as part of continual improvement. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 7.13 | What applicable tools and methodologies for investigation of the causes of underperformance and to support continual improvement are selected? | N/E | |  |
| 5.1.1 Leadership and commitment for the quality management system | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.0 | Show me how top management demonstrates leadership and commitment w.r.t. the QMS by taking accountability of the effectiveness of the QMS. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.1 | How is the quality policy and objectives established for the QMS and how are they compatible with the strategic direction and the organizational context? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.2 | How is the quality policy communicated within the organization? Show me how this is understood and applied. | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.3 | How are the requirements of the QMS integrated into the business processes? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.4 | How do you promote awareness of the process approach? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.5 | How do you ensure that resources needed for the QMS area available? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.6 | How do you communicate the importance of effective quality management? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.7 | How do you communicate the importance of conforming to the QMS requirements? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.8 | How do you ensure that the QMS achieves its intended results? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.9 | How do you engage, direct and support people to contribute to the effectiveness of the QMS? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.10 | How do you promote continual improvement? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.11 | How do you support other relevant management roles to demonstrate leadership in their areas of responsibility? | N/E | |  |
| 5.1.2 Customer focus | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.12 | Show me how top management demonstrates leadership and commitment w.r.t. customer focus ensuring requirements and applicable statutory and regulatory requirements are determined and met. How are risks and opportunities that can affect conformity of products and services determined? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.13 | How is the ability to enhance customer satisfaction determined and addressed? | N/E | |  |

| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|--------------------------|------|---|-------|---------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 2.14 | How is the focus on consistently providing products and services that meet customer and applicable statutory and regulatory requirements maintained? | N/E | |  |
| <input type="checkbox"/> | <input type="checkbox"/> | 2.15 | How is customer satisfaction maintained? | N/E | |  |
| 4.3 Determining the scope of the quality management system | | | | | | |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.7 | How have the boundaries and applicability of the QMS been used to establish the scope of the organization? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.8 | How have: The external and internal issues; The requirements of relevant interested parties and; The products and services of the organization been considered when determining the scope of the organization? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.9 | How has the application of the International Standard within the scope been determined, and how has it been applied by the organization? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.10 | How have any requirements of the International Standard been determined as not applicable? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.11 | Show me how conformity of products and services are not affected by this. | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.12 | Where is the scope available? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.13 | Where is it maintained as documented information? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.14 | Does it state what products and services are covered by the QMS? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.15 | Does it justify how instances of requirements of the QMS cannot be applied? | N/E | |  |
| 4.4 Quality management system and its processes | | | | | | |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.16 | How has the QMS been established? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.17 | Show me how this is implemented. | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.18 | How is it maintained and continually improved? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.19 | How have the processes been determined and how do they interact? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.20 | How have the processes been determined for the QMS? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.21 | What are the inputs and outputs for those processes? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.22 | What is the sequence and interaction of the processes? | N/E | |  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1.23 | What are the criteria, methods, measurement and related performance indicators needed to operate and control those processes? | N/E | |  |

| Status | NC/OFI | S.No | Checkpoint | Score | Remarks | Attachments |
|--|--------------------------|------|---|-------|---------|--|
| ✓ | <input type="checkbox"/> | 1.24 | What resources are needed and how are these made available? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.25 | How are responsibilities and authorities assigned for those processes? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.26 | How are risks and opportunities considered and what plans are made to implement actions to address them? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.27 | What methods are used to monitor, measure and evaluate processes and, if needed, what changes are made to achieve intended results? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.28 | How are opportunities to improve the processes and the QMS determined? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.29 | What documented information exists to support the operation of processes? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.30 | How is this documented information retained? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.31 | How is confidence that the processes are being carried out as planned determined? | N/E | |  <input type="checkbox"/> |
| 4.2 Understanding the needs and expectations of interested parties | | | | | | |
| ✓ | <input type="checkbox"/> | 1.3 | How have you determined what interested parties are relevant to the QMS? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.4 | How have you determined what requirements those parties have that are relevant to the QMS? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.5 | How has impact or potential impact been determined? | N/E | |  <input type="checkbox"/> |
| ✓ | <input type="checkbox"/> | 1.6 | How do you monitor and review the information about interested parties and their relevant requirements? | N/E | |  <input type="checkbox"/> |