QASEP MANUFACTURING CONTROLS SUBSYSTEM AUDIT JOB FUNCTION 11. 5

1. Purpose

This job function is created for the purpose that when CAA conducting a Quality Assurance System Evaluation Procedure (QASEP) Evaluation, the inspector can perform the manufacturing controls subsystem audit more effectively.

2.General

This job function is applied to the time when CAA conducts a QASEP evaluation.

3. Inspection Items

Major items for inspection and verification:

A. Part A. Statistical Quality Control-SQC :

(1). Has a statistical sampling inspection plan been established for acceptance of specified product characteristics at receiving inspection and during manufacture?

(2). Do the engineering and manufacturing organizations participate in the review, implementation, and maintenance of Statistical Quality Control (SQC) and Statically Process Control (SPC) techniques used for product acceptance?

(3). Has a satisfactory SPC method been established for acceptance of specific product characteristics?

(4). Are appropriate SPC control limits and subgroup selections used and maintained?

(5). Has a satisfactory PRE-control method been established for acceptance of specific product characteristics?

(6). Are pertinent personnel trained in statistical techniques?

B. Part B. Tool and Gauge :

(1). Does the specified equipment used for inspection and test have the degree of accuracy necessary to determine conformity of the characteristic being inspected?

(2). Are tools, gauge and equipment initially approved, periodically inspected and calibrated when applicable?

(3). Do standards used for calibration have adequate accuracy and are they traceable to a recognized international standards organization?

(4). Are tools and gauges protected, maintained and used in an acceptable environment, when specified, to ensure product conformity to CAA-approved data?

(5). When a product has been accepted by a significantly out-of-tolerance gauge, is an evaluation conducted to determine the need for corrective action?

(6). Are tool control procedures applied to NDI equipment?

C. Part C. Testing :
(1). Are test procedures/applicable instructions and subsequent changes, established, maintained, and adequately controlled?
(2). Do procedure ensure that the appropriate organizations participate in the review of test instructions or procedures?
(3). Are products/ parts that have been adjusted or reworked after test acceptance, retested to approval procedures?
(4). Are there procedures to ensure records are generated and maintained for completed tests of aircraft, engines, propellers, or parts thereof?

D. Part D. For Aircraft Manufacturers ONLY:
(1). Have flight test procedures and subsequent changes been submitted to and approved by the CAA?
(2). In the case of aircraft, is the audited facility using flight test pilot that have been fully qualified?
(3). In the case of aircraft, is the flight check-off form properly completed?

E. Part E. Nondestructive Inspection :
(1). Are NDI processes, including changes, properly documented, controlled, and reviewed for conformance with CAA-approved design data?
(2). Are NDI operators certified, recertified, and decertified by the audited facility and performing within their limits of authorization?
(3). Are applicable NDI procedures/ process specifications readily available and used by inspection personnel?
(4). Are the critical NDI parameters identified and controlled?
(5). Do procedures address NDI acceptance and rejection criteria?
(6). Is corrective action taken when an NDI process is found to be out-of-control?
(7). Are adequate test pieces and NDI known-defect samples available and identified to preclude introduction into the production system?
(8). Are NDI tanks and solutions checked for compliance with specifications?
(9). Are NDI inspection records generated and maintained?

F. Part F. Nonconforming Material:
(1). Is a Materials Review Board(MRB) established, documented and operational?
(2). Are nonconforming products/ parts identified, controlled, and dispositioned?
(3). Are MRB dispositions that are identified as major changes approved by the CAA

through the design approval process?
(4). Does upper management review and analyze nonconforming material data to detect adverse trends and determine appropriate levels of corrective and preventive action?
(5). Do procedures provide for engineering review of nonconforming material to determine if the documented nonconformance constitutes a major or minor change to the CAA-approved type design?
(6). Is corrective action (in-plant, at supplier, and in service) required where processes or procedures result in a nonconforming product/ part thereof and are the actions monitored for response, implementation and effectiveness?

4. References and Forms

A. References:

(1). QASEP Job Function 11

(2). Order 8100.7C Appendix 5

B. Forms: QASEP Checklist (Manufacturing Control Subsystem)

QASEP Checklist (Manufacturing Control Subsystem)

公司名稱(Company)		專案編號(Project No)	
檢查地點(Location)			
檢定證種類 (Production Basis)	☐ PC ☐TSOA ☐PMA ☐ Others		
執行時機 （Type of Activity）	☐ QASEP Evaluation ☐ PI Evaluation ☐ Product Audit ☐ Supplier Control Audit ☐ Production Approval		
執行時間（Activity Dates）	_____年____月____日至_____年____月____日		
產品名稱(Product)			
檢查主題(Subject)	第五分系統：製造管制 Subsystem 5: Manufacturing Controls		

項次 Item	檢 查 內 容 Contents	滿意 Sat	不滿意 Un-Sat	不適用 N/A	未評估 U/E	檢查員意見 Comments
Part A. 統計品質管制(Statistical Quality Control-SQC)						
501	接收檢驗及製程中之驗收特定產品特性時，是否建立統計抽樣檢驗計畫？ Has a statistical sampling inspection plan been established for acceptance of specified product characteristics at receiving inspection and during manufacture?					
502	工程部門及製造部門是否參與產品允收相關之統計品質管制及統計製程管制技術之審查、執行與維護？ Do the engineering and manufacturing organizations participate in the review, implementation, and maintenance of Statistical Quality Control (SQC) and Statically Process Control (SPC) techniques used for product acceptance?					

項次 Item	檢 查 內 容 Contents	滿意 Sat	不滿意 Un-Sat	不適用 N/A	未評估 U/E	檢查員意見 Comments
503	是否已有符合要求之統計製程管制方法，用來允收特定產品特性? Has a satisfactory SPC method been established for acceptance of specific product characteristics?					
504	是否運用並維護適當的統計製程管制管制界限及分批的準則？ Are appropriate SPC control limits and subgroup selections used and maintained?					
505	是否已有符合要求之 PRE-control 方法，用來允收特定產品特性? Has a satisfactory PRE-control method been established for acceptance of specific product characteristics?					
506	相關人員是否接受統計技術訓練？ Are pertinent personnel trained in statistical techniques?					
Part B. 工具及量具(Tool and Gauge)						
507	用來進行特定檢驗或測試的設備是否有足夠的精度，以決定被驗物符合設計要求？ Does the specified equipment used for inspection and test have the degree of accuracy necessary to determine conformity of the characteristic being inspected?					
508	工具、量具及設備之啟用是否經過核准，並且進行定期檢驗及校驗？ Are tools, gauge and equipment initially approved, periodically inspected and calibrated when applicable?					
509	校驗用的標準是否有足夠的精度，並且能追溯到國際標準組織？ Do standards used for calibration have adequate accuracy and are they traceable to a recognized international standards organization?					
510	工具及量具是否有適當的保護、維護，並在適當的環境條件下使用，以確保產品符合民航局核准資料？ Are tools and gauges protected, maintained and used in an acceptable environment, when specified, to ensure product conformity to CAA-approved data?					

項次 Item	檢 查 內 容 Contents	滿意 Sat	不滿意 Un-Sat	不適用 N/A	未評估 U/E	檢查員意見 Comments
511	當發現產品是經由明顯超出容差之量具所允收時，是否評估所需的改正行動？ When a product has been accepted by a significantly out-of-tolerance gauge, is an evaluation conducted to determine the need for corrective action?					
512	工具管制程序是否也應用於 NDI 設備？ Are tool control procedures applied to NDI equipment?					
Part C. 測試(Testing)						
513	測試程序、適用的指導書及後續的變更是否建立、維護並適當的管制？ Are test procedures/applicable instructions and subsequent changes, established, maintained, and adequately controlled?					
514	是否有的程序確保適當的部門參與測試指導書或程序的審查？ Do procedure ensure that the appropriate organizations participate in the review of test instructions or procedures?					
515	對於已完成允收測試之產品/零件進行調整或重工後，是否依照被核准的程序重新測試？ Are products/ parts that have been adjusted or reworked after test acceptance, retested to approval procedures?					
516	是否有程序確保飛機、引擎或螺旋槳成品之測試紀錄留存及維護？ Are there procedures to ensure records are generated and maintained for completed tests of aircraft, engines, propellers, or parts thereof?					
Part D.僅適用於飛機製造廠(For Aircraft Manufacturers ONLY)						
517	試飛程序及其後續變更是否送交民航局審查？ Have flight test procedures and subsequent changes been submitted to and approved by the CAA?					
518	受評設施是否雇用合格的試飛員進行試飛？ In the case of aircraft, is the audited facility using flight test pilot that have been fully qualified?					

項次 Item	檢 查 內 容 Contents	滿意 Sat	不滿意 Un-Sat	不適用 N/A	未評估 U/E	檢查員意見 Comments
519	是否正確填寫飛機之飛行檢查表？ In the case of aircraft, is the flight check-off form properly completed?					
Part E. 非破壞檢驗(Nondestructive Inspection)						
520	NDI 程序及其變更是否文件化及進行管制，並審查其符合民航局核准的設計資料？ Are NDI processes, including changes, properly documented, controlled, and reviewed for conformance with CAA-approved design data?					
521	NDI 之操作人員是否被受評設施驗證、重新驗證及取消資格，並且在其授權範圍內操作？ Are NDI operators certified, recertified, and decertified by the audited facility and performing within their limits of authorization?					
522	NDI 程序及規範是否可被檢驗人員容易取得及使用？ Are applicable NDI procedures/ process specifications readily available and used by inspection personnel?					
523	重要的 NDI 參數是否被標示並管制？ Are the critical NDI parameters identified and controlled?					
524	是否有程序說明 NDI 之允收標準？ Do procedures address NDI acceptance and rejection criteria?					
525	當發現 NDI 製程超出管制時是否採取改正措施？ Is corrective action taken when an NDI process is found to be out-of-control?					

項次 Item	檢 查 內 容 Contents	滿意 Sat	不滿意 Un-Sat	不適用 N/A	未評估 U/E	檢查員意見 Comments
526	是否有足夠的測試件或 NDI 已知缺陷樣本，並且有清楚的標示，以避免混入生產系統？ Are adequate test pieces and NDI known-defect samples available and identified to preclude introduction into the production system?					
527	是否檢查 NDI 設備槽及溶液，已確保其符合規範要求？ Are NDI tanks and solutions checked for compliance with specifications?					
528	NDI 的檢驗紀錄是否存檔及維護？ Are NDI inspection records generated and maintained?					
Part F. 不合格產品(Nonconforming Material)						
529	MRB 制度是否建立、文件化並運作？ Is a Materials Review Board(MRB) established, documented and operational?					
530	不合格之產品/零組件是否被標示、管制及處置？ Are nonconforming products/ parts identified, controlled, and dispositioned?					
531	當 MRB 的處置被視為大改時，是否經由設計核准程序由民航局核可？ Are MRB dispositions that are identified as major changes approved by the CAA through the design approval process?					
532	管理階層是否審查及分析不合格料件資料，找出不良的趨勢並訂出適當的改正及預防措施？ Does upper management review and analyze nonconforming material data to detect adverse trends and determine appropriate levels of corrective and preventive action?					

項次 Item	檢 查 內 容 Contents	滿 意 Sat	不 滿 意 Un-Sat	不 適 用 N/A	未 評 估 U/E	檢查員意見 Comments
533	是否有程序供工程審查，用以決定不符合事項屬於大改或小改？ Do procedures provide for engineering review of nonconforming material to determine if the documented nonconformance constitutes a major or minor change to the CAA-approved type design?					
534	當製程中產生不合格產品/零組件時，是否採取改正行動(包括廠內、供應商及使用中的產品)，並且有對應的行動監控其後續反應、執行情形及有效性？ Is corrective action (in-plant, at supplier, and in service) required where processes or procedures result in a nonconforming product / part thereof and are the actions monitored for response, implementation and effectiveness?					