OFFICE OF MANAGEMENT AND BUDGET

Coordination and Strategic Planning of the Federal Effort Against Intellectual Property Infringement: Request of the Intellectual Property Enforcement Coordinator for Public Comments Regarding the Joint Strategic Plan

Comments in Response to the Federal Register Request for Written Submissions from the Public, 75 Fed. Reg. 8137 Submitted by email to intellectualproperty@omb.eop.gov



Submitted by the Aviation Suppliers Association

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March 24, 2010

Thomas L. Stoll
Office of the Intellectual Property Enforcement Coordinator
Office of Management and Budget
Executive Office of the President

Dear Mr. Stoll:

Please accept these comments in response to the Request for Written Submissions from the Public that was published in the Federal Register at 75 Fed. Reg. 8137 (2010).

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Who is ASA?

Founded in 1993, the Aviation Suppliers Association (ASA) is the trade association that represents the aviation parts distribution industry. ASA has become known as an organization that fights for safety in the aviation marketplace.

Most of ASA's members are independent distributors who buy and sell aircraft parts. They serve as the logistical link between aircraft parts manufacturers and aircraft parts installers, like repair stations, air carriers, and the US Military Services. Aircraft parts distributors are not mere middlemen in the system. They contribute resources to warehouse parts safely, using appropriate environmental controls and tracking mechanisms, and they frequently provide value-added services like obtaining appropriate documentation to meet the varying regulatory requirements. Distributors operate in a marketplace that is surrounded by regulations and they frequently provide compliance services in diverse legal areas like hazardous materials, export, and traceability.

Summary of the Comments

Thank you for providing ASA with this opportunity to comment on the Federal effort against intellectual property infringement.

In the 1990s, ASA worked closely with the Federal Aviation Administration (FAA) to develop the Voluntary Industry Distributor Accreditation Program (VIDAP). This program encourages aircraft parts distributors to implement voluntary controls designed to protect aircraft parts safety. Although the VIDAP was originally developed to provide safety benefits to the aviation industry, it also provides protection against counterfeit aircraft parts.

The result of this program has been that many of the historical complaints about distribution of aircraft parts have been successfully addressed, and safety has been improved.

ASA believes that industry-sector-specific programs like this for distributors of other products could help mitigate some of the counterfeiting problems being reported in other industry sectors.

Comments

The FAA's Accreditation Program

In the 1990s, ASA worked closely with the Federal Aviation Administration (FAA) to develop the Voluntary Industry Distributor Accreditation Program (VIDAP), which is currently published in FAA Advisory Circular 00-56A (June 13, 2002).

Distributors accredited under the VIDAP implement voluntary quality-assurance measures. The measures include:

- Receiving inspection procedures that ensure that procured material, components, and
- documentation are traceable to a prior source and bear acceptable documentation that conforms to FAA-recommended requirements;
- Training to ensure that the quality system is properly executed;
- Procedures to ensure that employees who make quality determinations are qualified and trained;
- Procedures for segregation of incoming discrepant material.
- Procedures for controlling the calibration of measuring equipment;
- Shelf- life control systems;
- A system for assuring that technical data remains current and accessible;
- A system for inspection stamp control;
- A system to ensure that parts are adequately protected from damage and/or deterioration;
- A system to ensure that parts are stored according to appropriate environmental controls;
- A system for assuring accountability when documents are duplicated;
- Procedures for documenting redistribution of lots;
- Procedures for maintaining all documentation;
- Self-evaluation procedures for monitoring the effectiveness of the quality system;
- A recall control system;
- A system for third party-audits under a standard recognized by the FAA, and for notifying the third-party audit organization prior to making changes to the quality system;
- A system for hazardous material control.

The FAA publishes standards for these elements and then recognizes appropriate standards and accreditation organizations for accomplishing the accreditation to the standards.

These standards help to ensure that there are appropriate controls to protect the aircraft parts from damage or degradation, and to protect a chain of

documentation that demonstrates that the aircraft parts meet appropriate airworthiness standards.

Accredited companies are listed on a database controlled by the FAA (the database is managed by ASA on a voluntary basis). They are required to be reaudited periodically by the accrediting body (at least twice every three years).

An FAA Audit Report on the effectiveness of the Program is attached for your review.

Accreditation: Benefits for Preventing Counterfeiting

Although the VIDAP was originally developed to provide safety benefits to the aviation industry, it also provides protection against counterfeit aircraft parts. This is because the FAA published voluntary guidelines for 'acceptable documentation' associated with aircraft parts.

The documentation focus has lead to an industry paradigm in which companies naturally develop an audit trail that follows aircraft parts, and deviations from the norms in such audit trails are recognized upon receiving inspection. We have provided guidance in several cases where an ASA member recognized a traceability incongruity that resulted in discovery of inappropriate conduct.

Additional Comments In Response to Supplemental Questions

Comments In Response to Supplemental Questions 3

Identify specific existing processes involving cooperation between stakeholders and the U.S. Government (or between stakeholders and other governments) that have been particularly effective at curtailing or preventing infringement.

As discussed above, the Federal Aviation Administration (FAA) Voluntary Industry Distributor Accreditation Program (VIDAP), is currently published in FAA Advisory Circular 00-56A (June 13, 2002) and has been a positive force in aviation distribution for fifteen years. That program was developed as a cooperative effort between the FAA and industry to proactively address potential safety issues. The result of the program, though, has been to establish an infrastructure that has been successful in identifying unapproved parts (including counterfeit parts).

Comments In Response to Supplemental Questions 13

Suggest specific measures to further secure the domestic and international supply chains to minimize the threat posed by infringing goods or products.

We recommend partnering with industry groups to establish accreditation programs on the AC 00-56 model. Such program should be tailored to provide commercial, quality assurance, and safety benefits including the identification of counterfeits and other inappropriate parts. Such quality asurance-based programs can also be used to help bolster other forms of compliance, like export compliance, import compliance, etc.

Comments In Response to Supplemental Questions 17

Suggest specific strategies for reducing the threats to public health and safety caused by the use or consumption of infringing goods (for example, counterfeit drugs, medical devices, biologics, and ingested consumer products).

One of the most effective ways to stop infringing goods is to stop them before they reach the consumer. We recommend making the wholesale distribution communities active partners in this effort by encouraging them to participate in industry-specific voluntary accreditation programs. Such programs would encourage the establishment of quality assurance programs that encourage audit trails and quality assurance measures focused on regulatory compliance. In addition to the anti-counterfeiting benefits provided by such programs, . If developed and marketed appropriately, such programs can be promoted through market forces (competitive pressure from peers who have adopted the programs and market pressure from customers who prefer the programs).

There are many examples of successful implementation of such programs, including the FAA's Voluntary Industry Distributor Accreditation Program (VIDAP). This program has produced marked safety compliance results for a relatively low investment of government resources. It was marketed to the public through partnership with industry, and a customer-focused education initiative helped to ensure that customers recognized the positive steps being taken (voluntarily) by distributors, and rewarded those steps.

Conclusion

ASA believes that voluntary accreditation of distributors has been a successful mechanism for addressing a host of compliance issues; counterfeiting identification and prevention has been just one of the success stories associated with the FAA's voluntary accreditation program.

This model can be adapted to promote other U.S. government compliance objectives. Thus, an effective accreditation program might address more than mere intellectual property compliance - it can be used as a tool to educate and encourage companies in other compliance areas, like export compliance, tax accounting compliance, health and safety standards compliance, etc.

Using Safety Management Principles, such a program can also be used by a company to predict and prevent compliance obstacles, enhancing compliance through a proactive systems approach.

Your consideration of these comments is greatly appreciated.

Respectfully Submitted,

Jason Dickstein General Counsel

Aviation Suppliers Association



U.S. Department of Transportation

Federal Aviation Administration

Voluntary Industry Distributor Accreditation Program (AC 00-56)

FY 2004 Audit Report

Prepared by Aircraft Certification Service & Flight Standards Service

September 22, 2004

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EXECUTIVE SUMMARY

The Federal Aviation Administration (FAA) published Advisory Circular (AC) 00-56, Voluntary Industry Distributor Accreditation Program, in 1996. Since its publication, AC 00-56 has not been validated through a formal review process. Therefore, it was determined that the FAA would conduct an audit of an Accreditation Organization and observe the audit of two accredited distributors. The intent of the audits was to validate that both the Accreditation Organization and the accredited distributors were meeting the requirements of AC 00-56. The audits would also provide an opportunity to evaluate the effectiveness of AC 00-56.

An audit was conducted at the Aviation Suppliers Association (ASA), an Accreditation Organization, in Washington, DC on March 5, 2004. The results of the audit determined that ASA's quality system meets and exceeds the elements listed in AC 00-56, paragraph 8. There were no non-compliances to ASA's quality system procedures or AC 00-56.

An audit was conducted at an accredited distributor on May 25, 2004 by ASA, with the FAA in attendance. The results of the audit determined that the accredited distributor has a quality system that meets and exceeds the elements listed in AC 00-56, paragraph 6. There were no non-compliances to the accredited distributor's quality control manual, Aviation Suppliers Association Quality System Standard (ASA-100), or AC 00-56.

An audit was conducted at an accredited distributor on April 21, 2004, by Transonic Aviation Consultants, Inc. (TAC), with the FAA in attendance. TAC is an Accreditation Organization listed in AC 00-56. The results of the audit determined that the accredited distributor has a quality system that meets and exceeds the elements listed in AC 00-56, paragraph 6. There were no non-compliances to the accredited distributor's quality control manual, TAC's Aeronautical Parts Distributor Quality Assurance Standard (TAC 2000), or AC 00-56.

Overall, the results of the audits validate that AC 00-56 is working well. While participation in the program is voluntary, it is proving to be successful in that distributors, who are not regulated, are meeting a self-imposed standard. This program shows that collaboration between industry and the FAA has improved the level of certitude in aviation parts, and, therefore, has raised the level of safety through a cooperative effort.

INTRODUCTION

BACKGROUND

In 1993, the FAA Associate Administrator for Regulation and Certification strongly endorsed the voluntary industry oversight of distributors of civil aircraft parts rather than mandatory federal regulation. A task force was created comprised of representatives from the following organizations: FAA Aircraft Maintenance, Production, and Airworthiness Divisions; Aerospace Industries; Aeronautical Repair Station, Air Transport, Aircraft Electronics, Airline Pilots, Aviation Suppliers, Aviation Distributors and Manufacturers, Experimental Aircraft, General Aviation Manufacturers, National Air Transportation and National Business Aircraft Associations; and the International Association of Machinists and Aerospace Workers Union.

The task force prepared for the FAA's consideration a draft Advisory Circular (AC) on industry oversight of distributors, and in 1996 the FAA published AC 00-56, Voluntary Industry Distributor Accreditation Program (VIDAP), which formally established third party accreditation of distributors. This program was developed to provide certificate holders with the means to access the names of distributors that have met the quality elements of AC 00-56. In 2002, AC 00-56 was updated to reflect changes in the accreditation renewal cycle.

PURPOSE OF THE AUDIT

Since the original review and publication of AC 00-56 in 1996, and the subsequent update in 2002, the FAA has performed cursory reviews of the VIDAP. While the reviews by FAA and the feedback from industry all indicated that the program is successful, the FAA did not have a formal review process for validation of the program. Therefore, it was determined that the FAA would conduct an audit of an Accreditation Organization and observe the audit of two accredited distributors. The intent of the audits was to validate that both the Accreditation Organization and the accredited distributors are meeting the requirements of AC 00-56. Further, the audits would provide an opportunity to evaluate the effectiveness of AC 00-56. Recommendations derived from the audits will be considered when implementing future changes to the Advisory Circular.

SCOPE OF THE AUDIT

ACCREDITATION ORGANIZATION

An audit was conducted at ASA on March 5, 2004. The criteria utilized for evaluating the effectiveness of ASA's audit program was taken from AC 00-56, paragraph 8, Accreditation Organization Responsibilities. Prior to the evaluation, a checklist was generated which contained the system elements applicable to the Accreditation Organization responsibilities. The following system elements were evaluated:

- **a.** Accreditation Organizations shall have operating procedures that adequately address all elements of an effective accreditation program, to include audit review procedures, auditor qualifications, auditor training, internal auditing, issuance and withdrawal or reinstatement of certificates, internal document control, and appeals.
- **b.** Accreditation Organizations are responsible for auditing distributors to ensure compliance with both the requirements of their respective quality system standards and all the requirements set forth in the AC.
- **c.** Accreditation Organizations shall have procedures to enable them to periodically monitor the effectiveness of the distributor's quality system.
- **d.** Auditors utilized by an Accreditation Organization should have one of the following qualifications:
 - (1) Certification as an auditor by the American Society for Quality;
 - (2) Training as an auditor by the Coordinating Agency for Supplier Evaluation (C.A.S.E);
- (3) Training as an auditor by the National Aerospace and Defense Contractors Accreditation Program, or certification as an auditor by the International Organization for Standardization;
- (4) Past professional experience as a quality auditor for an air carrier, repair station, air agency, or under a distributor accredited under AC 00-56, Voluntary Industry Distributor Accreditation Program; and/or
 - (5) Past work as a FAA Aviation Safety Inspector with auditing experience.

- **e.** If the distributor is in compliance with the selected quality system standard and all elements of the AC, the Accreditation Organization shall provide the distributor with a letter certifying compliance to both.
- **f.** An accredited distributor under AC 00-56 shall be audited to the complete Acceptable Quality System Standard chosen at least once every 36 months with, at a minimum, one surveillance audit during the 36-month term to continue to participate in the voluntary industry accreditation program. Any letter certifying compliance with standards of AC 00-56 shall become invalid on the third anniversary of such certification, but this will not affect the letter's validity with respect to any other certifications made.

ACCREDITED DISTRIBUTORS

Audits were conducted at two accredited distributors by the respective Accreditation Organizations. The first audit was conducted at Delta Aviation, Inc. of Gaithersburg, MD, on April 21, 2004, by Transonic Aviation Consultants, Inc. (TAC) to the TAC 2000 standard. The second was conducted at International Aircraft Associates of Miami, FL, on May 25, 2004, by ASA to the ASA-100 standard. The Accreditation Organizations established their criteria based on the requirements of AC 00-56. The following elements constituted the minimum acceptable criteria for an accredited distributor's quality system:

- **a.** Receiving inspection procedures that ensure that procured material, components, and documentation are traceable to a prior source and bear acceptable documentation that conforms to at least one of the installer's requirements listed in Appendix 1 of AC 00-56.
- **b.** A system for training personnel to ensure that the quality system is properly executed, including the elements that make up the individual's job assignment.
- **c.** Administrative procedures that provide for the identification and qualifications of all employees that are authorized to make quality determinations, and assures that all such employees are qualified and properly trained.
 - **d.** A procedure for segregation of incoming discrepant material.
- **e.** Measuring equipment control that provides for appropriate storage, usage, and calibration when such equipment is required.
- **f.** A shelf-life control system that assures that the quality and technical criteria are met for each part stocked that is identified as having shelf life.

- **g.** Inspection stamp control that ensures control for issuance, usage, re-issuance, loss of, and accountability (when applicable).
- **h.** Inspection stamp control that ensures control for issuance, usage, re-issuance, loss of, and accountability (when applicable).
- **i.** Packaging control that ensures parts shipped are adequately protected from damage and/or deterioration.
- **j.** Environmental controls to ensure parts that require special environments are identified and stored accordingly.
- **k.** A procedure for assuring accountability when approval tags or other traceability documents are duplicated.
- **l.** A procedure for documenting redistribution of lots. Appropriate documentation would include, but not be limited to, lot and batch control, as well as control and verification of remaining inventory. The procedures should also include control and maintenance of all documentation.
- **m.** Procedures for maintaining documentation include, but are not limited to, the documents originally received with the parts being sold and shipped; the documents shipped with the parts; and any other documents used to establish the condition and origin of parts received and shipped.
- **n.** A procedure for monitoring the effectiveness of the distributor's quality system, including a self-evaluation program that identifies the individual(s) within the company responsible for self-audits, specifies the frequency of audits, identifies the applicable quality system standard, defines adequate records that must be created to document the audit, and describes a procedure for addressing corrective action where necessary.
- **o.** A recall control system that ensures recall notification can be adequately circulated to appropriate parts that have been shipped.
- **p.** A system for notifying the Accreditation Organization prior to implementation of any significant changes to the distributor's quality system, as determined by the Accreditation Organization.
- **q.** A system for hazardous material control and transport that meets the requirements of Title 49 of the Code of Federal Regulations (49 CFR).

RESULTS OF THE AUDIT

ACCREDITATION ORGANIZATION

Audit By FAA

An audit was conducted at ASA of Washington, DC on March 5, 2004 by the FAA. ASA is an Accreditation Organization listed in AC 00-56. The results of the audit determined that ASA has quality system procedures that include the elements listed in AC 00-56, paragraph 8. There were no non-compliances to ASA's quality system procedures or AC 00-56.

The Aviation Suppliers Association Quality System Standard (ASA-100) is the quality system standard that ASA uses to audit distributors. A comparison of ASA-100 and AC 00-56 shows that ASA-100 includes the elements listed in AC 00-56, paragraph 6.

ACCREDITED DISTRIBUTORS

Audit By ASA

An audit was conducted at International Aircraft Associates, Inc. (IAA) of Miami, FL on May 25, 2004 by ASA, with the FAA in attendance. ASA is an Accreditation Organization listed in AC 00-56. The results of the audit determined that IAA has a quality system that includes the elements listed in AC 00-56, paragraph 6. There were no non-compliances to IAA's quality control manual, ASA-100, or AC 00-56. IAA's procedures exceeded both the requirements of ASA-100 and AC 00-56.

Audit By TAC

An audit was conducted at Delta Aviation, Inc. of Gaithersburg, MD on April 21, 2004 by TAC, with the FAA in attendance. TAC is an Accreditation Organization listed in AC 00-56. The results of the audit determined that Delta Aviation, Inc. has a quality system that includes the elements listed in AC 00-56, paragraph 6. There were no non-compliances to Delta Aviation, Inc.'s Quality Control Manual, Transonic Aviation Consultants, Inc.'s Aeronautical Parts Distributor Quality Assurance Standard (TAC 2000), or AC 00-56. Delta Aviation, Inc.'s procedures exceeded both the requirements of TAC 2000 and AC 00-56.

CONCLUSIONS

The FAA chose to audit an Accreditation Organization and observe the audit of two accredited distributors participating in the Voluntary Industry Distributor Accreditation Program. The intent of the audits was to validate that both the Accreditation Organization and accredited distributors were meeting the requirements of AC 00-56. Further, the audits would provide an opportunity to evaluate the effectiveness of AC 00-56. Based upon the audits conducted at the Accreditation Organization and the two accredited distributors, the FAA has reached the following conclusions:

- AC 00-56 is a well-written guidance material that has helped industry to police itself inlieu of regulatory requirements.
- Distributors that choose to participate in the Voluntary Industry Distributor Accreditation Program, and the Accreditation Organizations that audit them are meeting a self-imposed higher standard than is required by AC 00-56.
- The Accreditation Organization that was audited has a quality system that far exceeds the requirements of AC 00-56.
- The two accredited distributors that were audited have quality systems that exceed both the Accreditation Organizations' standards and the AC 00-56 requirements.

Airlines, manufacturers, repair stations, and distributors all recognize the added benefits of participation in the Voluntary Industry Distributor Accreditation Program. Currently, there are 278 distributors that are participating. Many of these distributors have chosen to participate due to the added level of certainty that third-party certification offers their customers.

RECOMMENDATIONS

The FAA audit team has performed a review of AC 00-56, the Accreditation Organization's Quality System Standard, and accredited distributors' quality systems. The recommendations of the audit team are as follows:

- Consider updating/revising AC 00-56 to reflect a change in paragraph 10e, which states "The database manager will remove the information from the database within two business days from the date that the certification expires, or upon notification from an Accreditation Organization that it has revoked a distributor's certification or that the certificate has been surrendered." A more reasonable period for removal from the listing might be within 30 days.
- Remove appendix 2, Sample Database Letter, from AC 00-56, as it is misleading and confusing.
- Continue to monitor the Voluntary Industry Distributor Accreditation Program by conducting audits of both the Accreditation Organizations and the accredited distributors every two years. The lead for future audits should be the Maintenance Division, AFS-300, with the Production & Airworthiness Division, AIR-200 in a supporting role.
- FAA should promote the Voluntary Industry Distributor Accreditation Program by working with industry to encourage participation.

While participation in the program is voluntary, it is proving to be successful in that distributors who are not regulated are meeting a self-imposed standard. This program shows that collaboration between industry and the FAA has improved the level of certitude in aviation parts, and, therefore, has raised the level of safety through a cooperative effort. The FAA should review other programs for opportunities to involve industry in the policy-making process.