Counterfeit Parts Prevention Program Guidance Webinar

- The intent of this webinar is to define best practice to prevent proliferation of counterfeit goods in the supply chain. What will be discussed is applicable to manufacturers, MRO's and distribution organizations.
- I would like to point out the extent of your organization's formal compliance to any industry standards and government regulations, above and beyond these practices, may depend on your organization's customer contract requirements.
- Depending on your organization's role and position within the supply chain, your risk of receiving counterfeit parts or assemblies with counterfeit parts will vary. The more supply chain intermediaries (i.e. sub-tiers, distributors, customers, services etc) incorporating parts into products or assemblies the greater the risk.
- Depending on individual contracts for products and services, your organization may have multiple roles in the supply chain, and each needs to be considered.
- This webinar presentation is not intended to re-state industry and government regulations, but rather provide guidance and best practices. I will make reference to existing standards when/where applicable

Risk Management

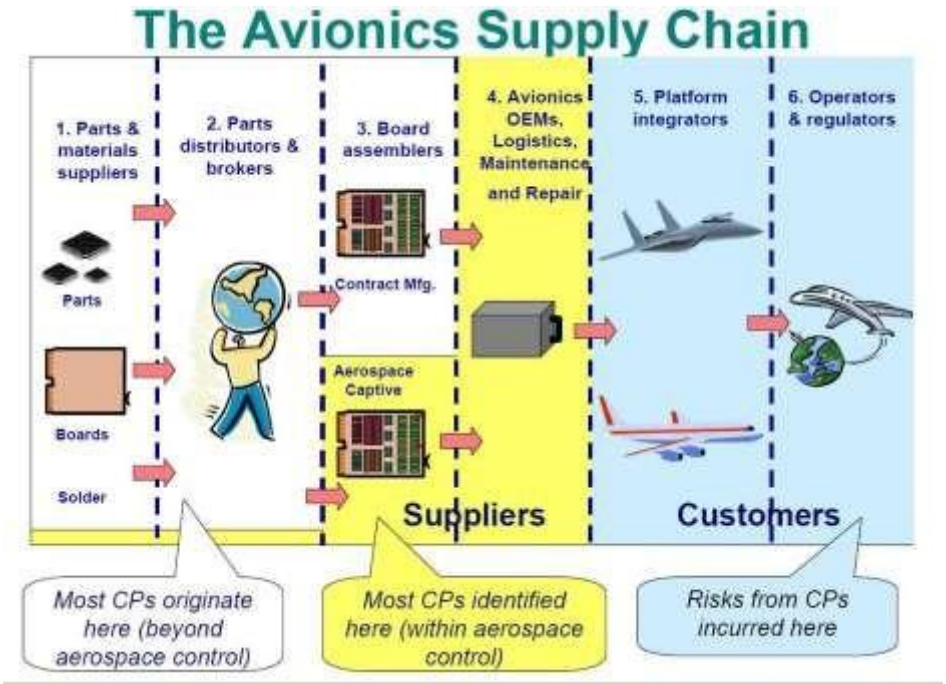
Counterfeit goods pose a significant risk to the supply chain, potentially resulting in loss of material, mission, or life.

Your risk of receiving counterfeit parts or assemblies with counterfeit parts will vary. The more supply chain intermediaries incorporating parts the greater your risk.

Risk: An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence. (IAQG Dictionary)

Risk: Risk is the future impact of a hazard that is not controlled or eliminated. (FAA Risk Management Handbook)

Risk Management



- Risk is dependent on both the sources of supply and the product application.
- There is risk associated with the procurement source. Buying directly from the original manufacturer poses less risk than buying from non-authorized sources, where traceability to the original manufacturer may have been lost or ignored.
- Then there is risk the parts themselves represent in the product. For example, an electronic part used in a personal computer may represent less risk than a similar part used on an aircraft. The more risk the part represents, the higher level of controls required to ensure the part will function in its intended use and environment.

Risk Management

Risk management weighs the likelihood that an event will occur against the consequence of the occurrence.

Risk assessment and mitigation are collaborative efforts between sub-assembly manufacturer, design authority, and the manufacturer of the end product.

Contract Review is an important part of the risk assessment and mitigation processes. The customer requirements often indicate the level of risk by the counterfeit part requirements flowed down. It is important that the correct functions within your organization review the contract language to confirm your organization's ability to comply with the customer's requirements.

Customer and/or Regulatory Requirements/Flow Down

Customers frequently specify design and production process requirements that they want to see applied to the product. These requirements can include counterfeit avoidance measures and regulatory requirements that the customer wants to see in place at its sub-tiers to lower its own risk of getting counterfeit material. It is important that your organization have a flow down process that receives the latest requirements from the customer and distributes them to the internal functions where compliance is to be demonstrated. When the customer is flowing down counterfeit avoidance requirements, it is important to:

- Ensure common understanding of customer counterfeit requirements. A protocol has to be established for reviewing the requirements with customer and where customer specialists and in-house specialists can discuss and agree on the interpretations of the flowed down requirements.
- Understand the customer's strategy on obsolescence management.

Customer and/or Regulatory Requirements/Flow Down

- Ensure all customer requirements are flowed down internally
- Ensure lifecycle (obsolescence management) planning and counterfeit avoidance planning are compliant with the customer requirements. The customer may want to review and approve these plans. During the design cycle the customer may also want to understand how product design tools are used to facilitate the planning effort.
- Ensure requirements are flowed down to all levels of the supply chain.
- Ensure sub-tiers understand and comply with the requirements.

Counterfeit Parts Control Plan

Having a counterfeit parts control plan is considered an industry “best practice”. Since the prevention of counterfeit parts affects multiple functions within your organization, it is useful to have a single counterfeit parts control plan to document these cross functional processes.

This Counterfeit Parts Control Plan documents the organization’s risk-based strategy used for identification, mitigation, disposition, detection, avoidance, and reporting of suspect and/or confirmed counterfeit goods.

The control plan should include the processes addressing the topics discussed in this presentation. Again, the extent of the processes depends on your organization’s position in the supply chain.

Counterfeit Parts Control Plan

The plan should include the following processes:

- Risk Assessment/Customer Requirements/Contract Review
- Customer Requirements/Flow Down
- Training
- Obsolescence
- Procurement
- Control of External Sources
- Traceability
- Material and Parts Control
- Verification of purchased/returned products
- Inspection/Test
- Investigation
- Handling of Suspect/Confirmed Counterfeit
- Reporting
- Monitoring counterfeit reporting, information, trends
- Internal/External Audits

Counterfeit Parts Control Plan

The plan should identify the roles and responsibilities as relates to each function. Key functions, again depend on your organization's size and location within the supply chain, include:

- Contracts
- Engineering
- Materials Management & Logistics
- Quality
- Supplier Management & Procurement

Training

A key strategic element of mitigating the risks posed by counterfeit parts and materials is through on-going training for all relevant personnel. This training will increase awareness of the potential of counterfeit parts helping prevent their introduction into the supply chain.

Relevant personnel are any persons involved in any way with parts/material. This includes personnel with responsibility for management, design, contracts, procurement, inspection and testing, and any person who deals with the parts/materials.

General awareness training is appropriate for all relevant employees. In addition, detailed training for specific functional roles and responsibilities is appropriate and may be required by your customer.

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Training

Elements of training should include:

- General awareness training
  - Background information:
    - Definition of counterfeit materials and parts
    - The origins of counterfeit materials and parts and how they enter the supply chain
    - Vulnerabilities to counterfeit parts (e.g. obsolete and hard-to-find parts)
    - New laws and regulations
    - Examples of counterfeit parts or materiel
  - Strategies to Eliminate Counterfeit
    - Avoidance
      - Procuring from Authorized Sources
    - Detection
      - Making Sure Counterfeits are Stopped prior to integration in higher level assembly
    - Mitigation
      - Minimizing Risk and Damage to the project or customer use
    - Disposition
      - Decide on Proper Action & Resolution through Disposition

Training

Additional Training should be considered for the following personnel:

- Receiving/Incoming Inspection
- Purchasing
- Engineering
- Program/Project Management
- Stock management
- Assembly/MRO personnel
- Operators
- In-process Inspection
- Quality Assurance Inspection
- Internal Auditors

Obsolescence

Due to diminishing manufacturing source issues, many industries may have difficulty in continuing to obtain manufactured products designed years ago to support fielded and new systems. The challenge of avoiding counterfeit parts and materials occurs when customers are obliged to purchase out of production parts to support existing products. Choosing materials that are likely to become obsolete in the lifetime of the product's production can cause procurement departments to seek out sources of supply that have higher inherent risks of providing counterfeit material. To lower these risks you are encouraged to:

Develop Parts/Material Plan

Avoid single sources when possible – Single sources can expose the supply chain to many risks. Fire or natural disasters, war and civil uprisings can interrupt supply. In addition, the source can go out of business or change.
(Continued on next slide)

Obsolescence

business or change ownership or move the production location to an unauthorized/illegal location. Any of these events can force procurement to look at inventories of material that may not be traceable back to the Original Component Manufacturer (OCM)/Original Equipment Manufacturer (OEM), elevating the risk of obtaining counterfeit material.

Determine product/component availability – Even multi sourced components embodied in the end-product can quickly go out of production at all sources as new technology replaces them or other market factors force them out of the market. Some analysis of the likelihood of losing the supply of components needs to be conducted before committing the design to that component.

Drive common part usage – Using common parts with broad industry demand provides a higher level of assurance that the parts will not become obsolete. In addition, if demand is broad it is likely that multiple sources will exist.

Obsolescence

Determine aftermarket supply – The aftermarket tends to have higher counterfeit risks because of the ‘Grey Market’ shops that offer parts with unapproved repairs or ‘new’ parts of suspect origin. Ideally the supply of new parts to the aftermarket should be through the same source as the authorized production source. Lifetime buys for sustainment should also be considered while parts are still available from authorized sources,

If parts are coming from repair sources, they should be working to approved repair schemes and have the proper documentation to show the part is airworthy. If parts are coming from repair sources within an OCM/OEM, they should be working to Engineering approved repair schemes and Engineering should be involved in the approval of these repair shops.

If part obsolescence increases the counterfeit risk, it is important to coordinate with your customer to ensure the needs over the product lifecycle are met.

Procurement

Procurement can be divided into three components –

Component One - Supplier Approval,

Component Two - Source Selection, and

Component Three - Purchase Order Placement.

Supplier Approval is the process of selecting suppliers to be on the approved supplier list. Source Selection is the process of selecting a supplier for specific order from the approved supplier list. Purchase Order Placement is the process for preparing and issuing the purchase order.

Procurement – Supplier Approval

Supplier risk mitigation is accomplished via the supplier approval process and is the first line of defense against purchasing counterfeit parts.

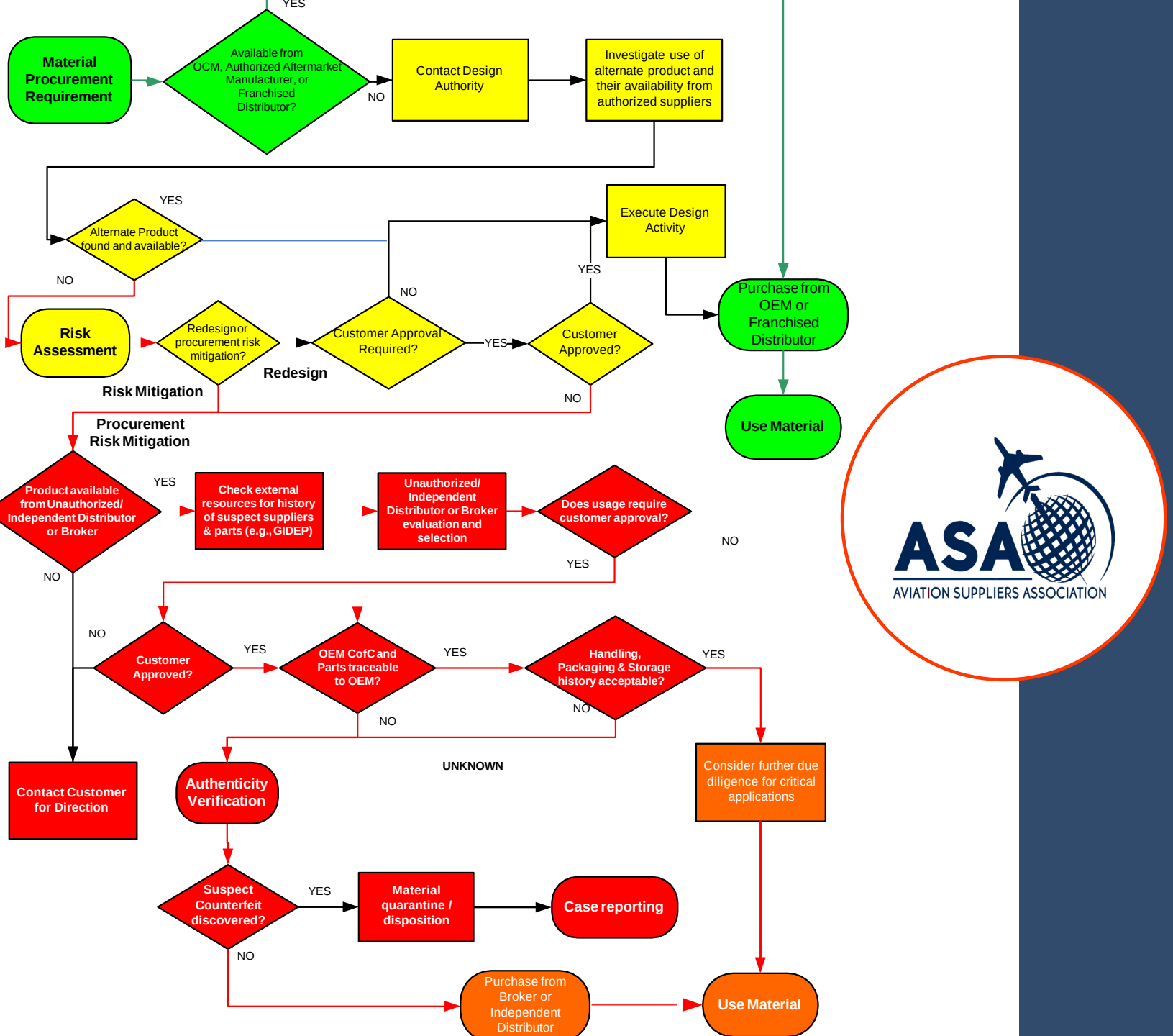
Historical data has shown that there is a higher risk of counterfeit parts when parts are procured from unauthorized or independent distributors. Procuring parts from original manufacturers and their authorized distributors provides a much higher likelihood of ensuring genuine products.

Besides normal “due diligence” in the supplier approval process, there are additional sources you can use to review potential distributors. Examples are:

- Anti-Counterfeiting Forum
- Electronic Retailers Association International (ERAI).
- FAA Unapproved parts list
- Government - Industry Data Exchange Program (GIDEP)

When independent distributors or brokers are the only source of parts, * extra measures must be performed to ensure the purchase of authentic and approved parts.

Procurement – Supplier Approval



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Procurement – Source Selection

When selecting a distributor, broker, or supplier, the different risks associated with their selection should be recognized. As stated above, there is less risk when procuring from the Original Component Manufacturer (OCM, Authorized aftermarket manufacturer, etc.) or authorized/franchised distributor, than when procuring from an independent distributor or broker. Due to these differing risk factors, these risks must be evaluated and mitigated to ensure confidence that counterfeit parts are prevented and/or identified.

Before you purchase from distributors, you need to understand the type of distributor they are. There are two types of distributors:

- Authorized/Franchised
- Unauthorized or Independent distributors/Brokers

Procurement – Source Selection

- “Authorized/Franchised” distributors are authorized by OCM/OEM (Original Component/Equipment Manufacturer) to market, store and ship their product(s) as part of a distribution agreement. AS6496 is an example of requirements for mitigating counterfeit products in the authorized distribution supply chain.

- “Unauthorized” or “Independent” distributors/“Brokers” refer to distributors that have no formal relationship with the OCM/OEM. *

An “authorized reseller” is not the same as an authorized distributor and clarification is dependent on the OCM’s formal distribution agreement.

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Procurement – Source Selection

Utilizing Unauthorized/Independent Distributors or Brokers may require additional verification activity to ensure the product provided is authentic. Some regulations (e.g. DFARS 252.246-7008) or industry standards (AS5553) require a formal risk mitigation plan (with defined testing and acceptance criteria) when procuring parts from “independent sources”, as defined in those standards.

If the source selected is not already on the approved supplier list, the supplier approval process should also be performed.

Procurement – PO Placement

Specific requirements may be used to maximize the likelihood of being provided authentic material. Depending on the risk factors involved, the purchasing requirements will differ. The Request for Quote (RFQ) and the Purchase Order should define the product, documentation, traceability, and testing requirements, including where applicable, the use of approved sources for materials and/or processes. It should also include any other customer requirements that need to be flowed down through the supply chain. *

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Traceability

Traceability serves several functions in counterfeit part mitigation. The first function is to track a part from the manufacturer through intermediaries to minimize the opportunity of procuring or introducing a counterfeit part into the supply chain.

The next function traceability serves is to be able to track and identify any suspect or confirmed counterfeit parts that are in-process or in service so that the parts can be recalled and replaced as necessary. It allows the organization to quickly quarantine parts in service, replace the affected parts, and return the products to service. This minimizes both field impact and production impact. *

There are trade-offs between the cost of providing the traceability and the cost avoidance if production or in-service product is affected. Hence the level of traceability needed may vary depending on application, supply chain environment, and the risk to the end user. Examples include very detailed part traceability (e.g. serial number), lot traceability where the part usage can be identified and limited to a particular production lot or batch of deliverable hardware, or some other method.

Traceability

The Request for Quote (RFQ or equivalent) and the Purchase Order should define the traceability requirements as applicable. Aerospace fasteners, for example, require date and lot code because they can be traced back to the manufacturer. When purchasing parts from a distributor, knowledge of the required documentation is essential. A CofC (Certificate of Conformance) may include traceability information but can be easily counterfeited so reliance on this document alone is not foolproof.

Unless full product traceability to the OCM/OEM is provided with the part, extra visual inspection as well as testing will provide an increased level of confidence that the parts will function as required. This will require a level of communication between the procurement and engineering organizations to assess the level of risk and develop an inspection and testing plan appropriate to the level of risk the part poses in the product.

Traceability

Upon receipt, traceability documentation should be evaluated in an effort to identify suspect material. The verification activities shall be appropriate to the product risk.

- Identity: Original manufacturer, part number, date code, lot number, serial number, batch number, etc.
- Pedigree: Origin, ownership history, storage, handling, physical condition, previous use, etc.
- Inspection and test results

Customer contract or legislation may require that traceability records be maintained. This can be a short period (a few years) but could be as long as the life of the product, which could be many decades.

Part Authentication

As stated earlier in the *Risk Management* section, the best method to avoid counterfeit parts is to purchase the parts directly from the original manufacturer. This is not always possible or practical. It is not just the parts that can be counterfeited. Counterfeiting can also occur in the documentation attesting to the authenticity of a part. Therefore, your organization should establish inspection and test criteria as applicable to detect possible counterfeits.

Your organization's quality manual will already address product verification activities to assure an externally provided product conforms to its specified requirements. The applicable quality requirement flow down and the level of purchased product controls, are determined in accordance with the effect the purchased product has on subsequent product realization and the end product. In other words, verification activities are performed based on customer requirements, source selection risk, component risk, and application criticality. Likewise, risk determines the most appropriate methods of inspection and test.

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Part Authentication

Some examples of inspection activities are: review of data deliverables (certificates of conformity, test results, process control documentation, first article reports, etc.), independent laboratory tests, product and/or process audits/assessments, product inspection at a supplier's facility, inspection/verification of the product and accompanying documentation upon receipt, and formal delegation of product acceptance to the supplier.

Determination of Suspect Counterfeit

During the verification process, indicators that a part may be counterfeit may be identified. Per the definition, a Suspect Counterfeit Part is a part for which there is objective and credible evidence indicating that it is likely counterfeit. If there is an indication of suspect counterfeit part(s), the situation will require additional During the verification process, indicators that a part may be counterfeit may be identified. Per the definition, a Suspect Counterfeit Part is a part for which there is objective and credible evidence indicating that it is likely counterfeit. If there is an indication of suspect counterfeit part(s), the situation will require additional Inspection/Screening process is to analyze the results in order to prepare a disposition and final report.

Determination of Suspect Counterfeit

The interpretation of inspection results should be documented in accordance with the specific test/inspection method(s) used. Analysis may require a forensics approach. There could be distinct and subtle indications that suggest that an item is suspect counterfeit. Indications for counterfeiting and quality defects from the authentic manufacturer and other quality related issues (e.g., poor storage and handling) can often be confused, leading to false positive or false negative results. Care should be taken to resolve inconclusive findings and to distinguish between counterfeit indications and quality indications. The sum-total of the observations from the complete test/inspection sequence is what establishes the overall conclusion.

Determination of Suspect Counterfeit

One indicator from the parts or packaging may be sufficient if it is conclusive enough. If there are enough indicators that lead to a conclusion with a reasonable level of confidence that the parts are more likely suspect counterfeit, you may want to consult with the authentic manufacturers. There are times when they are willing to provide pertinent information to the decision making. If the indicator(s) lead to a conclusion that the parts contain quality issues, then document the quality issues in the final review and relevant information that led you to believe the final determination is quality related rather than counterfeit related.

If parts do not exhibit indicators that lead to a conclusion with a reasonable level of confidence that the parts are suspect/counterfeit, then the final determination that the parts passed required testing and that there was no evidence of counterfeiting based on the testing/inspection performed.

Handling of Suspect/Confirmed Counterfeit Parts

Your organization's Quality Management System (QMS) typically addresses the control of nonconforming material, including the segregation and quarantine of parts and associated documentation until dispositioned.

Additional areas to address include:

- Containment of any related parts or material, including product which may already have shipped to the customer.
- Notification from external sources potentially impacting your product. This may include reviewing GIDEP Reports and other industry sources related to suspect/counterfeit parts.
- Detailed reporting information on who to notify to ensure customer and regulatory requirements are met.

Suspect counterfeit and counterfeit parts should be treated as nonconforming material and quarantined to prevent use or re-entry into the supply chain until such parts are inspected and/or tested, and relevant documentation researched and verified. Only parts confirmed as authentic and meeting customer requirements can be dispositioned for release and subsequent use.

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Handling of Suspect/Confirmed Counterfeit Parts

In the event the part/material is counterfeit, the part and all information relating to the purchase of the part, including points of contact, company name and address should be collected and retained in the event it is needed for use in an investigation. This may include investigations by law enforcement officials.

Counterfeit parts not needed as evidence for an investigation should be completely destroyed/mutilated to keep the parts from re-entering the supply chain.

Reporting

The counterfeit parts risk impacts all levels of the supply chain. By working together, OEMs, distributors, customers, and suppliers become more aware of the problems and more effectively deal with counterfeits and counterfeiters. Reporting suspect counterfeit parts helps limit the proliferation and use of counterfeit parts across the supply chain by:

- Alerting others of suspect counterfeit parts by part numbers and types and by lot or batch numbers if known
- Identifying sources of counterfeit parts
- Highlighting methods of counterfeiting
- Sharing Inspection and testing used for identification and verification.
- Helping other players in the supply chain adequately assess risk and improve quality and reliability
- Reducing the resources needed to maintain awareness of counterfeit issues by establishing a cooperative effort to exchange technical information

Reporting

Suppliers should have a process in place on how and where to report suspected or confirmed counterfeit parts or materials. This process should include who to contact and what (if any) organizations to report the information to. All appropriate personnel should be aware of the proper reporting process for suspect/counterfeit Parts.

All counterfeit / suspect counterfeit parts should be reported internally within the organization. Ensure the reporting of suspect counterfeit parts across all appropriate business units and functions, including Legal/Contracts.

Customers should be notified of the discovery of any suspect/counterfeit parts. This is especially important if the discovery affects product which has already shipped. Customer requirements may specify the reporting methods and timeframe.

Reporting

A best industry practice is to report suspect/counterfeit parts externally to the appropriate authorities/ law enforcement agencies. It is the responsibility of all suppliers in the supply chain and benefits the entire aviation, space and defense industry. There may be national or local laws which require this reporting.

Another best practice for external reporting is reporting to centralized databases/reporting sources which gather information relating to suspect/counterfeit parts. These industry accessible, centralized databases allow companies to research parts and suppliers/distributors before purchasing from them. This may be required by your contract.

Examples of centralized databases are (see Appendix A for more information):

- Anti-Counterfeiting Forum
- ERAI
- FAA Suspect Unapproved Parts
- GIDEP

Monitoring information and trends

Recently, Quality Management Systems such as 91XX have included counterfeit prevention requirements and other Government level requirements and counterfeit law have been published. Suppliers need to have a method to monitor counterfeit activity relative to the types of products they procure to reduce the risk of inputting counterfeit material into the supply chain. These methods can include

- Ensuring positive, trusting relationships with your suppliers and distributors
- Searches on the internet
- Monitoring of information from reporting sources such as GIDEP, ERAI, Anti-Counterfeiting Forum.
- Membership/participation in societies, industry groups, and forums

Internal/External Audits

Counterfeit avoidance has been a requirement since its release and we now see this is included in 91XX and is reviewed as part of QMS audits. Customers and regulatory authorities may also audit your counterfeit avoidance systems and practices. Auditing the Counterfeit Avoidance program allows an organization's management to know how robust the program is and how well-prepared employees are to look out for and deal with suspect or proven counterfeit parts. Auditing can also demonstrate that the organization has a system adequate to the customer's requirements. Any weaknesses identified need to be addressed in accordance with the organization's policies and procedures.

Counterfeit Parts Reporting and Monitoring Agencies

NOTE: Any website information provided was accurate at the time of publication but may have changed since that time.

GIDEP (www.gidep.org) does not charge for their service although, an account is required and there are restrictions on GIDEP membership. Other limitations also apply for GIDEP reporting and accessibility. Prior to publishing a GIDEP Alert, the submitted data is thoroughly reviewed and the offending business is given an opportunity to rebut. This process may take more time but it assures its accuracy and the protection of its information.

ERAI's (www.erai.com) database is a subscription-based product. Anyone can pay the fee and have access to the data. Some advantages of ERAI are that it provides a database of aliases for a distributor's name. This function is useful with counterfeit part reports that have been discovered against one company.

IDEA (www.idofea.org) is a resource for distributors to find relevant quality information and to participate in advancing industry ethics, ensure customer satisfaction, establish standards and promote education. The purpose of IDEA is to promote the independent distribution industry through a media advocacy campaign, to improve the quality of products and services through a quality certification program, educational seminars, and conferences, and to promote the study, development, and implementation of techniques and methods designed to improve the business of independent distributors.

The Anti-Counterfeiting Forum (www.anticounterfeitingforum.org.uk) helps to exchange, develop and disseminate best practice and intelligence to mitigate against the threat of counterfeits in the electronic and electrical supply chain.

Government Reporting Methods

FAA

Suspected counterfeit component issues can be e-mailed to the Aviation Safety Hotline office.

See webpage http://www.faa.gov/contact/safety_hotline/

EASA

EASA issue Safety Information Bulletins (SIBs) on potential hazards which may include reporting of counterfeit or fraudulent components

The European Aviation Safety Agency is located at Ottoplatz 1, D-50679 Koeln, Germany, tel

+49 221 8999 000, info@easa.europa.eu and has a webpage http://easa.europa.eu/home.php .

EASA controls Design Organisation Approvals (DOA), Production Organisations Approvals (POA) and Maintenance Organisations Approvals (MOA).

EU counterfeit reporting

Counterfeit reporting within the EU should be reported locally. The Europa webpage contains forms and details of how to process national and EU wide applications for IP action by customs authorities

The Europa webpage for the EU Taxations and Customs Union entitled 'How can right holders protect themselves from counterfeiting and piracy' provides details and forms for reporting counterfeit activities, see webpage http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/right_holders/index_en.htm

Thank You for attending!

Questions?