About the Speaker

Sarah MacLeod was instrumental in the formation of the Aeronautical Repair Station Association (ARSA) and is currently its executive director. As such, Ms. MacLeod is assistant chair for air carrier and general aviation maintenance of the FAA's Aviation Rulemaking Advisory Committee (ARAC), a post she has held since 1996.

She is a managing member of the law firm of Obadal, Filler, MacLeod & Klein, P.L.C., where she is engaged in the legal representation of foreign and domestic air carriers, aircraft maintenance, and alteration facilities, distributors, pilots, and other individuals and companies.

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Law, regulations, guidance and government policies change; while this material is regularly updated, its accuracy is not guaranteed.

In addition, application to a particular situation is always dependent on the facts and circumstances involved.

The use of this material is therefore at your own risk.
Course Overview

• Know the rules
  – Regulations
  – Contract

• Establishing your relationship
  – With the government
  – With the customer

• Preparing for audits
  – Internally
  – From the government
  – From the customer

• Making the most of audits
Know the Rules

• Your role
  – Certificate requirements
    o Acquiring the certificate
    o Maintaining certification requirements
  – Performance requirements
    o Under the regulations
    o Under the contract

• The government role
  – Certification and Surveillance
  – Enforcement

• The customer’s role
  – Regulatory requirements
  – Contractual requirements
Your Role

Certification Requirements

• Acquiring the certificate
  – The applicant must show
  – The FAA must find
  – Certification based upon documented
    o Knowledge,
    o Experience,
    o Facilities, and
    o Capabilities
Your Role
Certification Requirements

– Certificate is a privilege not a right

– You must show – the Administrator must find
  o Showing must be based on the regulations
  o Finding must be based on the regulations, guidance, policy and qualifications

– Both must know the rules
  o Regulations
  o Guidance
  o Policy
Your Role
Certification Requirements

• Maintaining the certificate
  – Certificate holder is responsible for
    o The basic requirements of the certificate
    o Maintaining the basic and on-going requirements
    • Housing, facilities, equipment, etc.
    • Personnel and/or individual requirements
  – Contracts are often based upon maintaining the regulatory certificate
Performance Requirements Under the Contract

• General requirements
  – Required to hold an appropriate certificate
  – Required to have and maintain adequate
    ◦ Quality control
    ◦ Quality assurance
  – Required work product
    ◦ Scope of work and authorization
    ◦ Quality of work
Performance Requirements Under the Contract

• General requirements
  – Required records
    o Financial
    o Quality or work product
  – Warranties
    o Financial
    o Quality
  – Turn time
  – Subcontractor approval
  – Audit authority
Performance Requirements Under the Contract

• Specific requirements
  – ISO registration
  – Customer specified
    o Quality system
    o Design approval
    o Records and recordkeeping
  – Data exchange and protection
    o Proprietary rights
    o Copyright
The Government Role
Certification and Surveillance

• Certification
  – Review the application
    o Ensure completeness
    o Advise of discrepancies or acceptance
  – Review the documentation and/or facilities
    o Compare to regulatory, guidance and policy requirements
    o Document discrepancies, reasons for discrepancies or acceptance and reason for acceptance
  – Issue the appropriate certificate
The Government Role
Certification and Surveillance

• Surveillance
  – Review documentation
    o Application
    o FAA record of compliance
    o Manuals
  – Review guidance and policy for appropriate scope of audit or surveillance activity
    o National program requirements
    o Special emphasis inspections
The Government Role
Certification and Surveillance

- Surveillance
  - Establish appropriate scope and timing of surveillance activity
  - Review certification basis and requirements of the particular certificate holder
    o Parts 61, 63 and 67 knowledge, experience, qualifications and medical
    o Part 65 knowledge, experience, location, extent of work being performed
    o Part 145 housing, facilities, equipment, tools, personnel, data and inspection system
The Government Role Certification and Surveillance

- Surveillance
  - Review records required to show compliance
  - Observe activity
  - Record activities
    - Type of inspection
    - List of discrepancies
    - Program specific requirements
  - Notify certificate holder of discrepancies
The Government Role
Enforcement

• The right to take action for non-compliance
  – The Act
    o Fines and penalties
    o Certificate actions
    o Criminal actions
  – The Code of Federal Regulations (Title 14)
  – The hazardous material regulations (Title 49)

• The right to investigate
  – Subpoena power
  – Depositions
  – Hearings
The Government Role Enforcement

• The rules
  – Title 14 CFR part 13
  – Title 49 CFR parts 171-180, 821, 830 and 831

• FAA guidance and policy
  – 2150.3B Compliance and Enforcement Program
  – Legal memoranda
  – NTSB requirements
The Government Role
Enforcement

• The legal standard
  – Burden of proof
    o Civil: Preponderance of the evidence
    o Criminal: Beyond a reasonable doubt
  – Burden applies to EVERY element of the charge

• The legal parameters
  – Must respect YOUR rights
    o The right against self-incrimination
    o The right to have representation
  – Must be investigating/enforcing the CFRs
The Customer’s Role

Regulatory Requirements

• Records
  – Manufacturing
  – Operation
  – Maintenance
• Type of customer will dictate
  – Continuous analysis and surveillance
  – Drug and alcohol testing
  – More or different records
The Customer’s Role
Contract Requirements

• Quality control system
  – Specific data and specifications
  – Specific facilities, equipment and tooling

• Quality assurance system
  – Self audit functions
  – Customer specific requirements

• Records
  – Specific form
  – Specific manner
  – Specific length of time
Establishing Your Relationship With the Government

- Know the rules
  - Read the rules, guidance and policy
  - Maintain a library of the information
- Document every contact
  - Telephone calls and visits:
    - Date and time
    - Person(s) involved
    - Items discussed
    - Issues resolved
    - Signature of person making the record
Establishing Your Relationship With the Government

• Document every contact
  – Requests for information, clarification, waivers, changes or any other “official” action by correspondence
    o State the regulatory basis for the request or action
    o State the specific issue(s) clearly and concisely
    o State the desired action or result
    o If appropriate, provide a time schedule
    o Send by certified mail, return receipt or some other method where receipt can be verified
Establishing Your Relationship With the Government

• Ensure proper follow up
  – Report your own progress
  – Request report on the government’s progress
  – Provide written verification of changes in the same manner the original request was made

• Develop standard letters for continued activities
  – Changes to operations specifications
  – Changes to manuals
Establishing Your Relationship With the Government

• Establish relationships
  – Meet the local office management
    o Provide (company or individual) profile
    o Outline (company or individual) activities
  – Hold regular meetings with the local office
  – Hold scheduled meetings with principals
  – Invite local office to training sessions
  – Share information with local office
Establishing Your Relationship With the Government

• Keep accurate and complete records
  – Application, any changes or adjustments to your certificate
  – Obtain a copy of your file from your local office
  – Records of
    o Telephone calls
    o “Visits”
      • Surveillance
      • Audits
      • Drop-ins
• Be professional and courteous at all times
Establishing Your Relationship With the Customer

• Make a record for each customer
• Obtain a copy of every contract
  – Review quality control and assurance requirements
  – Review record and recordkeeping requirements
  – Review certification requirements
  – Make a record of discrepancies from your systems and requirements
  – Obtain deviation authority for any discrepancies or adjust own system
Establishing Your Relationship With the Customer

• Establish a contact point with the customer
  – Through sales department
  – Through quality department

• Establish a “quality” relationship with appropriate individuals
  – Present your company’s “quality” profile
    o Quality manuals and procedures
    o Quality records and reports
  – Protect your company’s information from customer exposure
Preparing for Audits
The Self Audit

• Purpose of any audit is to verify that—
  – You say what you do
  – You do what you say?
  – You document that you do what you say you do
  – Your procedures are effective and in compliance with the law and customer specifications
Preparing for Audits
The Self Audit

• An effective audit
  – Reviews regulations, guidance, policy and procedures
  – Reviews contracts, manuals, documents and data
  – Reviews selected records, observes operations, inspects facilities, equipment and interviews personnel
  – Documents results OBJECTIVELY; cites the WRITTEN and VERIFIED standard or requirement
Preparing for Audits
The Self Audit

- Obtain objective evidence
  - Cite and/or attach copy of regulation, manual or other document not followed
  - Take pictures as appropriate (i.e., particularly appropriate when evaluating “housekeeping” issues)
  - Attach evidence to audit report or retain in a separate file
  - Avoid opinion/subjectivity where possible; be factual
  - Make sure your report is concise and clear!
Preparing for Audits
From Anyone

• Record retention policy
  – Put the policy in writing
  – Establish retention periods for each type of document
  – Apply it to all types of records (government, customers, third party accrediting bodies, etc.)
  – For regulatory purposes, records can be disposed of when they are no longer required
    ○ But, remember to consider commercial issues
    ○ Never dispose of records during a government inspection or investigation without consulting counsel!
Preparing for Audits From Anyone

• Conduct preliminary audit several weeks prior to real thing (use same checklist or job aids the government will use)

• Correct all findings promptly and evaluate apparent violations under the self-disclosure program

• Tie up any loose ends with local governing office (obtain necessary written approvals, send letters on issues that require a paper trail)
Preparing for Audits From Anyone

• Review the basics
  – Review record retention policy
  – Identify regulatory or contractual requirements
  – Review past audits, internal, external and with the particular entity coming “this time”

• Conduct self audit

• Correct all findings promptly

• Tie up any loose ends with the government or customer’s quality or sales department
Surviving the Audit
Be Prepared

- Circulate appropriate information on the extent and nature of the audit to—
  - Company managers
  - People on the floor
- Brief company managers
- Prepare briefing for inspectors
Surviving the Audit
Be Prepared

• Establish procedures to manage the audit
  – Designate key personnel in each area/corporate team leader
  – Prepare forms to document inspection activity
  – Establish location of Liaison Center
  – Obtain necessary equipment and supplies for Liaison Center
  – Designate rooms for auditors/inspectors
Surviving the Audit
Be Prepared

• Prepare or provide information for each auditor/inspector
  – Facts about company
    ◦ Identify senior staff
    ◦ Organization charts
  – Compliance initiatives/other positive actions
  – List of area coordinators
  – Location of required records
  – Document request forms
Surviving the Audit
Managing the Audit

• Making documents available
  – Keep track of everything provided or copied!
  – All documents should be copied by company personnel (do not allow customers or the government to bring in their own copy machines)
  – Auditors/inspectors should not be allowed to rummage through company file cabinets in search of records
  – Auditors/inspectors should sign out original records for review ONLY in a designated area
Surviving the Audit
Managing the Audit

• Daily meetings
  – Hold meeting at the end of the inspection day with key company personnel should be in attendance
  – Address each new item brought up that day and determine if (what) action will be taken
    o Obtain more information, possibly providing it to the auditor/inspector or team leader
    o Prepare to contest the finding
    o Begin implementing corrective action
    o Prepare necessary documents
  – Follow up with inspector/auditor/team
Surviving the Audit
Managing the Audit

• Dealing with auditors/inspectors
  – Always provide escort while audit team is on the premises
  – Have your most knowledgeable people present
  – Take extensive notes of any questions or interviews
    o Who was questioned
    o What was asked
    o What was the response
Surviving the Audit
Managing the Audit

• Dealing with auditors/inspectors
  – Be helpful, but don’t sing!
  – DON’T ACT GUILTY!
    ○ Answer the questions asked
    ○ Don’t GUESS or VOLUNTEER
      • Let me find that out
      • Let’s look in the manual
      • So-and-so knows that better
    ○ If you do not understand the question, ask that it be clarified
Surviving the Audit
Managing the Audit

• Dealing with auditors/inspectors
  – BE PROFESSIONAL – STAY CALM
  – Don’t be hostile even if things escalate
  – Report inappropriate behavior by auditors/inspectors to the company team leader
  – Follow up audit team inquiries promptly
  – Do not change company procedures based on verbal comments made by auditors or inspectors
Surviving the Audit
Managing the Audit

• Dealing with auditors/inspectors
  – Do NOT allow you or your people to be bullied
    ▪ The government CANNOT take your certificate without legal action
    ▪ You CAN ask for representation during a government investigation from a fellow worker or lawyer
  – Do NOT let a group of auditors/inspectors “gang up” on one of your employees
Surviving the Audit
Responding to the Audit

• Respond in writing
  – We don’t admit to doing anything wrong
  – We’ll fix it right away
  – We’ll never do it again

• In the response
  – Restate each finding exactly as it was stated
  – Follow with the company’s response
Surviving the Audit
Responding to the Audit

• If finding is wrong, state reasons and provide evidence

• Provide specific and concise descriptions of actions, if any, that will be taken

• Specify dates by which actions will be completed and meet those dates

• Attach substantiating documents

• Review prior to submission
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