

Internal Audits Demystified

Christine Ruther
C&R Engineering, Inc.

TCB Council – February 22, 2006

Why Internal Audits?

- You must (Guide 65 – 4.7)
- You want to
 - Prep for outside audits (ANSI, etc.)
 - View on business
 - Doing what we say we'll do?
 - Meeting company goals?
 - Customer service
 - Efficiency
 - ...

Selecting Auditors

- Need more than 1
 - Auditors must be independent of area audited
 - Someone must audit the audit program
- Auditor qualities to consider
 - Curious – especially why & how
 - Confident
 - Willing to ask potentially “foolish” questions
 - Willing to ask business related questions
 - Willing to speak frankly to management

Auditor Knowledge

- Quality system rules
 - Guide 65, ISO 17025, etc.
 - ISO 10011-1 / ISO 10993-1
 - TCB Manual(s)
- Standards & regulations
 - CISPR, ETSI, IEC, etc.
 - FCC, IC, iDA, etc.

Conducting an Internal Audit

- Must address
 - Quality system rules
 - Standards & regulations
- Must follow ISO 10011-1 / ISO 10993-1
 - Audit plan (including informing auditee)
 - Opening meeting
 - Audit (checklist highly recommended)
 - Closing meeting (including informing of results)
 - File audit results
 - Ensure corrective actions are timely & appropriate

Audit Timing & Planning

- Cover all elements annually
 - IAF guidance says “annually”
 - Technically could be longer but ...
- How to cover elements
 - By element (follow standard)
 - By functional area
- When to cover elements
(all at once or piecemeal)

All at Once

- Advantages
 - Big picture shows itself
 - Disruption to normal work is done and gone
- Disadvantages
 - System can skew in interim
- Recommendations
 - Do 6 months after outside assessment
 - Supplement with useful mini-reviews
(i.e., sample evaluation/surveillance files)

Piecemeal

- Advantages
 - Frequent review of work
 - (little time to skew, reminders of quality system to all)
 - Shorter disruptions may make business sense
- Disadvantages
 - Accidental omission of elements
- Recommendations
 - Have overview plan to ensure all elements are covered

Audit Hints

- When in doubt, read
 - Quality system rules
 - Guide 65, ISO 17025, etc.
 - ISO 10011-1 / ISO 10993-1
 - TCB Manual(s)
 - Standards & regulations
 - CISPR, ETSI, IEC, etc.
 - FCC, IC, iDA, etc.
- Presentation follows clauses of Guide 65
(not likely how real audit will flow)

4.1 – General Provisions

- Non-discriminatory
 - Any can apply?
 - Equal pricing?
 - Same application of rules?
 - Test lab has 17025 for data submitted?
 - Same review process for same application type?
- Guide 7 – certification rules
 - Applies to standards/rules developers
 - May apply to TCB in limited ways

4.1 – General Provisions (con't)

- Cert reqs, evaluation & cert decision
 - Limited to scope of certification
 - Know what is “off limits” (i.e., FCC exclusion list)
 - Know scope of accreditation
 - Verify clear representation to applicant
 - Acting as TCB?
 - Acting as agent to regulatory body?

4.2 - Organization

- Impartiality (no ties to \$\$ or pride)
- Define who is in charge (& verify authority)
 - Who ensures policies are implemented
 - Who oversees finances
- Legal entity (business license, etc.)
- Decision on cert is dif. from evaluation
- Liability coverage (general and E&O)

4.2 – Organization (con't)

- Financial stability
 - Napkin calculation
 - Ensuring impartiality if rely on lab revenue
 - Covering surveillance costs
- Personnel to handle work
 - Number and qualifications
 - Napkin calculation
 - Consider all levels of personnel involved
(administrative, evaluation/test, certification, etc.)

4.2 – Organization (con't)

- Certification work must be unique from other activities
- Free from outside pressures
 - Stock ownership
 - Previous/current employment
 - Involved with test (may not be obvious)
 - Bonus/pay structure
 - Pay for files reviewed or turn times
 - Pay by hour

4.2 – Organization (con't)

- Committees involved
 - (1 person can be a committee)
- Confidentiality, objectivity & impartiality
 - May not supply/design, advise/consult, etc.
 - Formal agreement with employees
- Complaints, appeals & disputes
 - (more later)

4.3 – Operation

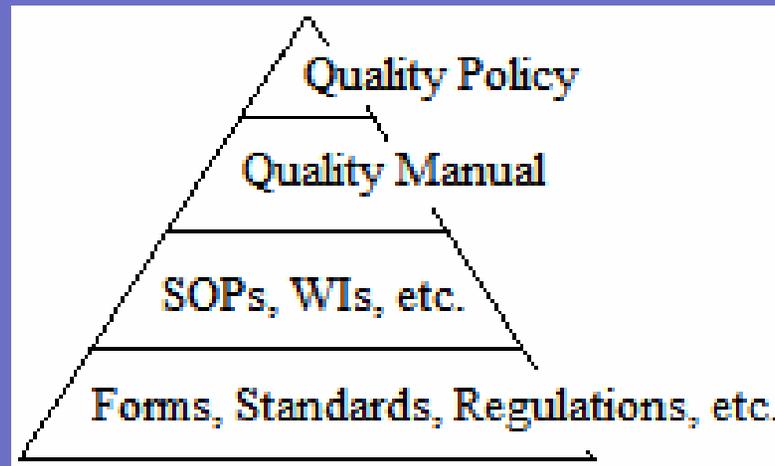
- Define work to be done
 - Evaluation
 - Testing
 - Sampling

4.4 – Subcontracting

- ANSI decision
 - Contract employee works entirely under TCB rules as any employee does
 - Subcontractor operates under own rules
 - Contract is required (scope, confid, impart, etc.)
 - TCB ensures competence (audit, rev of cert, etc.)
 - Client must provide consent to use
 - Commonly used for SAR (likely to expand to other speciality tests such as those under iDA)

4.5 – Quality System

- Quality policy
 - *Define*
 - Ensure implemented and understood
- Quality system – doc'd & available



4.5 – Quality System (con't)

- Must defined “mgmt rep”
 - Ensures Q. system is established, implemented & maintained
 - Reports to mgmt on system performance
 - Direct access to highest authority

4.5.3 – Quality Manual

- Items must be included directly or by reference:
 - Description of legal status
 - Names, qualifications, experience & titles of senior executives & CB personnel
 - Doc control procedures
 - Recruitment, selection & training of CB personnel & monitoring of their performance

4.6 – Grant, Maintain, etc.

- Need procedure(s) to define each activity
 - Grant (evaluation & certification)
 - Maintain (surveillance, contract duties, etc.)
 - Extend (define work needed)
 - Withdrawal (define work needed)
- Suspension is (so far) not an TCB option

4.7.1 – Internal Audits

Congratulations on being here

and not falling asleep
(or at least not snoring loudly)

4.7.2 – Management Review

- Annually or more often is reasonable
- Reviews are to ensure
 - Continuing suitability & effectiveness to
 - Quality system
 - Standards & regulations
 - Consideration needs to be given to
 - Adequacy of resources (people, equip, \$\$, etc.)
 - Coverage of all points (i.e., Guide 65 contents)
 - Document review

4.8.1 – Document

- Must provide, update and send upon req
 - Items listed in a-g
 - Others use flow chart outlining Q System
(+ some verbiage on other points)
 - For directory (g) can usually point to reg body
- Review & approve docs
 - Define who approves & release process
 - Include electronic media (forms, info, etc.)
- Control copies of documents (incl. stnds)

4.9 – Records

- Shows processes were followed
- Ensure integrity (who, what, where, etc.)
- Ensure confidentiality
 - Electronic records
 - Keep confidential through disposal/destruction
- Retention time in schemes (FCC, ID, etc.)

4.10 – Confidentiality

- Must formally state rules
 - Can't assume everyone has same ideas
 - Need to set expectations (i.e., public cmprts)
- Employees & subcontractors must agree to in writing

5.1 – General Personnel

- Must be competent
- Describe duties & responsibilities
 - For each entity (name, title, function, etc.)
 - Keep up to date
 - Hint – can be useful when people transition

5.2 – Qualification Criteria

- Must define minimum competency for each TCB entity
- Each person must SIGN to commit to
 - Comply with all TCB rule
 - Confidentiality
 - Independence from commercial & other interest
 - Declare prior & present associations
- Subcontractors are also subject to this

5.2 – Qualification Criteria (con't)

- Personnel records
 - Qualifications & professional status
 - Experience & Training
 - (be creative & keep current)
 - Performance appraisal
 - Make valuable (i.e., be technical in part)
 - Cover everyone (i.e., president)
- *Take care to avoid unnecessary sharing of confidential info (i.e., salary)*

6 – Changes in Cert Reqs

- Generally n/a (rules come from regulators)
- Consider for changes in
 - Application process
 - Certification process
(handling of files or changes to files)
- Required if private mark issued

7 – Appeals, Complaints, Disputes

- What fits here?
 - Client error correction requests
 - All regulatory feedback (i.e., FCC TR's)
 - Errors in judgment regarding file
- Consider classifying to streamline handling
 - Typos, most TR's, & other fast issues
 - Judgment errors, process problems, & other longer term issues
- **Must document**
 - **Actions taken**
 - **Effectiveness of actions**

8 – Application

- Give to applicant
 - Evaluation & certification procedures
 - Reqs for certification including rights & duties
 - Rights: release product, apply label, etc.
 - Duties: provide info., pay fees, surveillance, etc.
- Application must address all in 8.2
 - Could be more than one document (i.e., contract with application form – *just define*)
 - Must include: compliance with scheme reqs, supply info needed, etc.

15 – Complaints to Suppliers

- Require applicant to
 - Keep records of complaints against products
 - If compliance related
 - Share with TCB upon request
 - Document actions if certification is affected
- Put in application with others?

9 – Preparation for Evaluation

- Must review and document
 - Reqs defined, documented & understood
 - Differences in understanding are resolved
 - TCB has capability (authorized, people/equip, language, etc.)
- Must have evaluation plan (i.e., checklists)
- Must have appropriate working documents
 - Access to regulations & standards
 - Checklists (i.e., FCC template)

10 – Evaluation

- Pandora's box (1 paragraph, 32 words)
- Evaluate against “rules of the scheme”
 - FCC
 - IC
 - iDA
 - etc.
- *IMO: Often not sufficient detail in internal audits*

11 – Evaluation Report

- Must report evaluation findings (P, F, NA)
- Must tell applicant and allow response
- Need only re-eval parts in question

12 – Decision on Certification

- Base on eval & “any other relevant info”
- Can’t be delegated
- If all okay, issue cert
 - Informing of FCC grant
 - Must issue certs for IC, iDA, etc.
- For amendments, TCB determines what, if any, evaluation is needed
 - Recommend doc process (who, when, etc.)

13 – Surveillance

- Must have SOP that aligns with regs
(who, what, when, where, how)
- Document surveillance activities
 - Poorly defined
 - Think about what is reasonable
 - Lab rpt style (what, who, when with cal equip, etc.)
 - Compare to initial results?
 - Proud to show to FCC, et. al.?

14 – Licenses, Certs & Marks

- Control
 - Certs/marks used by applicant
(FCC grant, IC ID, etc.)
 - Certs/marks used by TCB
(ANSI, NVLAP, etc.)
- Take actions if problems found

Internal Audits

- Perform with curiosity
- Keep business goals in mind
- Use the information to improve