

**Federal Communications Commission  
Office of Engineering and Technology  
Laboratory Division Public Draft Review**

**Draft Laboratory Division Publications Report**

**Title:** TCB Post-Market Surveillance

**Short Title:** TCB Post-Market Surveillance

**Reason:** New Revision of Attachment

**Publication:** 610077

**Keyword/Subject:** Post-Market Surveillance Responsibilities for TCBs

**First Category:** Telecommunications Certification Bodies (TCBs)

**Second Category:** Requirements for TCBs – Part 2.962

**Third Category:**

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**Question:**

What are the post market surveillance requirements for a TCB?

**Answer:**

Section 2.962(g) of the FCC Rules requires a TCB conduct appropriate post-market surveillance activities in accordance with ISO/IEC Guide 65. The requirements for Telecommunication Certification Bodies (TCBs) were specified in the Commission's Report and Order (R&O) in GEN Docket 98-68 (FCC 98-338), adopted on December 17, 1998. Further guidance on the requirements for TCBs was given in Public Notice DA 99-1640.

The FCC provides additional information regarding Accreditation Requirements for Telecommunication Certification Bodies in GEN Docket 98-68 (FCC 98-92), released on May 18, 1998.

Attached below is an OET laboratory administrative guidance document [610077 D01 TCB Post Market Surveillance v05](#)

**Attachment List:**

[610077 D01 TCB Post Market Surveillance v05](#)

**Attachment**

**TCB Post-Market Surveillance**

One of the responsibilities of a Telecommunication Certification Body (TCB) is to conduct appropriate post-market surveillance activities in accordance with ISO/IEC Guide 65. These activities are based on Section 2.962(g)(2) which requires the TCB to perform post-market surveillance activities based on type testing of products that the TCB has certified.<sup>1</sup> The following are typical processes that may be used to meet this obligation:

**Sample Test Plan.** TCBs shall have a plan that demonstrates how they intend to ensure that the proper number of samples will be tested. As part of this plan, TCBs shall notify the applicant/grantee in writing of the sampling requirement and advise them that they are required to make provision to have ‘production’ samples available for at least one year after the last production date and that they may be required to submit the equipment for post-market surveillance testing. These samples may be requested, at any time, by either the TCB or the Commission.<sup>2</sup>

**Sample Selection.** Samples audited by a TCB are selected from the products certified by that TCB. When selecting the samples to be audited, the TCB should give consideration to the following:

- (1) New technologies.
- (2) New applicant.
- (3) New testing laboratory.
- (4) Products with a history of non-compliance.
- (5) Products whose test report may be sufficient for approval, but may raise a question of continued compliance.
- (6) Requests from the FCC for an audit to be performed on specific product types.
- (7) Potential impact on licensed radio services, the public switched telephone network (PSTN) or a user, from a non-compliant device.

**Sample Rate.** The number of samples audited by the TCB shall be based on the following:

- (1) The total number of products audited by the TCB shall consist of at least five percent of the total number of products certified by the TCB, under Scope A –

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<sup>1</sup> The requirements for Telecommunication Certification Bodies (TCBs) were specified in the Commission’s Report and Order (R&O) in GEN Docket 98-68 (FCC 98-338), adopted on December 17, 1998. Further guidance on the requirements for TCBs was given in Public Notice DA 99-1640, *FCC Provides Further Information on the Accreditation Requirements for Telecommunication Certification Bodies GEN Docket 98-68*, released on August 17, 1999.

<sup>2</sup> See 47 C.F.R. §§ 2.943, 2.945 and 2.946.

Unlicensed Radio Frequency Devices and Scope B – Licensed Radio Service Equipment, for the calendar year. A ‘product’ is considered to be the equipment covered under a single FCC ID.<sup>3</sup> Surveillance shall be performed on a proportional basis based on the number of products authorized per TCB Scopes A and B. The number of products audited shall also represent the same proportion of FCC recognized accredited test laboratory reports versus Section 2.948 listed test laboratory reports as the total number of products certified for a given year.

- (2) The total number of products audited by the TCB under Scope C – Telephone Terminal Equipment, shall consist of at least two percent of the total number of products certified under Scope C by the TCB for the calendar year.
- (3) As part of the TCB’s post-market surveillance responsibility, a TCB is required to submit an annual report of their post-market surveillance activities for the calendar year to the FCC by January 31<sup>st</sup> of the following year. The post-market surveillance report is for all audits conducted by the TCB in the previous calendar year.
- (4) If the TCB has certified products subject to RF Radiation Exposure requirements, then such products shall be included in the total number of samples audited. At least one percent of the products subject to SAR measurements and certified by the TCB for the surveillance year shall be audited. A sample tested for the one percent SAR surveillance can also count as satisfying surveillance under the five percent EMC surveillance requirement, if the TCB also tests the EMC parameters.
- (5) When calculating the number of samples to be audited, the number shall be rounded up to the next whole number.
- (6) A product certified in a prior surveillance year, but tested in the present surveillance year, will be credited as surveillance in the present surveillance year.

**Obtain Sample.** The TCB shall obtain a sample by one of the following methods:

- (1) Request the grantee submit a sample of the product certified.

The FCC should be notified when the grantee refuses or fails to comply with a request. The grantee is expected to have samples available to respond to a request from the TCB or the FCC. The TCB is expected to notify the grantee of the requirement for having ‘production’ samples available as noted under **Sample Test Plan** above.

Stating that a device is no longer manufactured is not a sufficient justification for not providing a sample. Also, stating that the device will not be marketed in the United States does not absolve the grantee of the requirement to provide

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<sup>3</sup> A composite device may be covered by multiple applications for equipment authorization. When auditing a composite device the TCB shall review each of the applications and all of the capabilities of the grant(s).

post grant production samples upon request by the TCB or the FCC.

An applicant may not be required to maintain a sample on hand if the production run is very limited in quantity (*i.e.*, 10 or fewer) or for some other reason that makes keeping a production sample on hand onerous to the applicant. In this case, the justification to avoid maintaining a sample on hand for surveillance purposes shall be documented in the application records. A determination by the TCB that the justification is acceptable to not keep a production sample on hand shall also be included as part of the application records.

- (2) Purchase a sample of the product from the marketplace.

**Evaluation.** The sample shall be evaluated by the TCB to determine compliance with the Commission's Rules.

- (1) The sample shall be tested to qualify as meeting the FCC post-market surveillance requirements. Complete testing to all of the Commission's requirements is not required; however, sufficient testing shall be performed to allow the TCB to evaluate those requirements most likely to be in non-compliance and provide a high level of confidence that the sample complies with the FCC Rules.
- (2) Testing may be performed at either the TCB's testing facilities or at a subcontracted test facility. Use of subcontracted test facilities is subject to the conditions in ISO/IEC Guide 65 clause 4.4. The TCB shall take full responsibility for the work and is responsible for ensuring that the subcontracted body is competent to perform the testing, and complies with all applicable requirements.
- (3) The test data and sample shall be compared to the information submitted in the Certification filing. All information should be consistent. The internal photos of the sample shall also be inspected to ensure that there have been no modifications to the test sample. All radio parameters such as power, frequency and operational modes shall be consistent. Any substantial variation shall be reported to the FCC.
- (4) The TCB shall examine the sample to determine compliance with the Commission's labeling and user instruction requirements.
- (5) The test report documenting surveillance shall specify key technical parameters such as the tests that were conducted, the test instrumentation used, whether the test instrumentation was within calibration, the test methods used, the test site used; and the report shall be signed by the person(s) performing the tests.
- (6) A review and decision by the 'certification body personnel' shall be made, after completion of the evaluation, as to whether the sample complies with the applicable FCC requirements.

**Follow-up Actions.** The following actions are to be taken based on the finding of the surveillance audit:

- (1) If during the audit process the TCB finds that a sample fails to comply with the FCC requirements, the TCB shall immediately notify the grantee and the FCC. A follow-up report shall be provided to the FCC by the TCB, within 30 days of the notification of non-compliance, of the action taken, or that will be taken, by the grantee to correct the situation.
- (2) The TCB shall file, with the FCC, an annual report of all surveillance audits performed. The data shall be provided with details on the surveillance performed for each of the TCB Scopes (A, B, and C).
- (3) If the TCB finds that the sample submitted for surveillance is different from the product described in the Certification application, the TCB shall immediately notify the grantee and the FCC.

Each TCB is required to submit an annual report of their post-market surveillance activities for the calendar year to the FCC by January 31<sup>st</sup> of the following year.

The TCB shall submit reports of surveillance activities carried out by the TCB, within 30 days of a request by the FCC. In support of a compliance investigation, the TCB may also be required to test a sample of a product certified by the TCB, and report its findings to the FCC within 30 days.

The TCB may perform other types of surveillance, provided such activities are no more burdensome on the grantee than type testing.<sup>4</sup> Types of surveillance other than type testing are subject to review and acceptance by the FCC.

### **Change Notice:**

610077 D01 TCB Post-Market Surveillance v05 replaces 610077 D01 TCB Post-Market Surveillance v04r01:

General changes (list includes substantive changes, not editorial changes):

- (1) Production samples are required to be kept available for at least one year after the last production date of the device.
- (2) The TCB Post-Market Surveillance reporting period has been changed to be a calendar year with the report due by January 31<sup>st</sup> of the following year.

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<sup>4</sup> See 47 C.F.R §2.962(b). The certification system shall be based on type testing as identified in sub-clause 1.2(a) of ISO/IEC Guide 65. Certification shall normally be based on testing no more than one unmodified representative sample of each product type for which certification is sought.