

Internal Audit: Global Program Continuity During Adverse Business Conditions

Speaker: Bill Eyer
Agilent Technologies
2125 East Katella Avenue Suite 300
Anaheim, California 92806
Phone: (714) 935-5488 Fax: (714) 935-5603
bill_eyer@agilent.com

Author: Bill Eyer
Agilent Technologies

Abstract

In times of restricted expense budgets and perhaps reduced human resources, it may be opportune to introduce some new thinking and methodology in managing your internal audit programs. Customers and internal groups alike may be expecting more than your internal audit program can realistically deliver, so where to focus and what to do? This session is designed to introduce and discuss the global internal audit program structure and methodology utilized within the support organization of Agilent Technologies' Electronic Products and Solutions Group (EPSG). The current audit program has been modified and updated to provide improved program management during very difficult business conditions. Updating strategy, more effective audit planning, developing new methods, and better overall program administration are some of the modifications now built into our global audit program. We'll discuss the design criteria for our audit program and how we resolved many of the key issues, some of which resulted in cost savings.

1 Driving Forces for Change

Over the last two years several events have contributed to a general world wide economic slowdown with a somewhat severe impact to the industries in the high tech environment. Agilent Technologies, being no exception to this situation, found itself needing to focus on all operational business areas, looking for cost savings and greater opportunities to leverage best practices. Spending and expense controls were implemented at all levels with management approval required for all purchasing. Most travel was curtailed and business meetings converted to various teleconferencing methods. In addition, it became necessary to initiate a company wide workforce management program to better balance our business performance with our overall employee headcount. These initiatives began to place a significant strain on our ability to manage an internal audit program and achieve the results we had expected in terms of our objectives.

Our audit program was producing reasonable results, however at annual review sessions it was noted that program changes would be required if continual improvements were to be realized. The advent of ISO 17025 and its effect on an internal audit program was another factor that

needed serious consideration. In light of the expense programs initiated by the company and a desire to improve our current methods and results, it became necessary to review our entire audit program and strategy. The balance of this paper addresses the structure of our organization, the audit program, its subsequent changes, and some of the results we observed.

2 Agilent Technologies Global Support Organization

Agilent Technologies is a global company that designs and manufactures products in several key segments including Test and Measurement, Life Science/Chemical, Automated Test Equipment, Communication Solutions, and Semiconductor Products. The Test and Measurement segment is more commonly known as the Electronic Products and Solutions Group (EPSG). EPSG consists of many business and product generation units and a global repair and calibration organization known as Support Solutions Unit (SSU). Figure 1 depicts the global locations for many of the manufacturing and support sites.

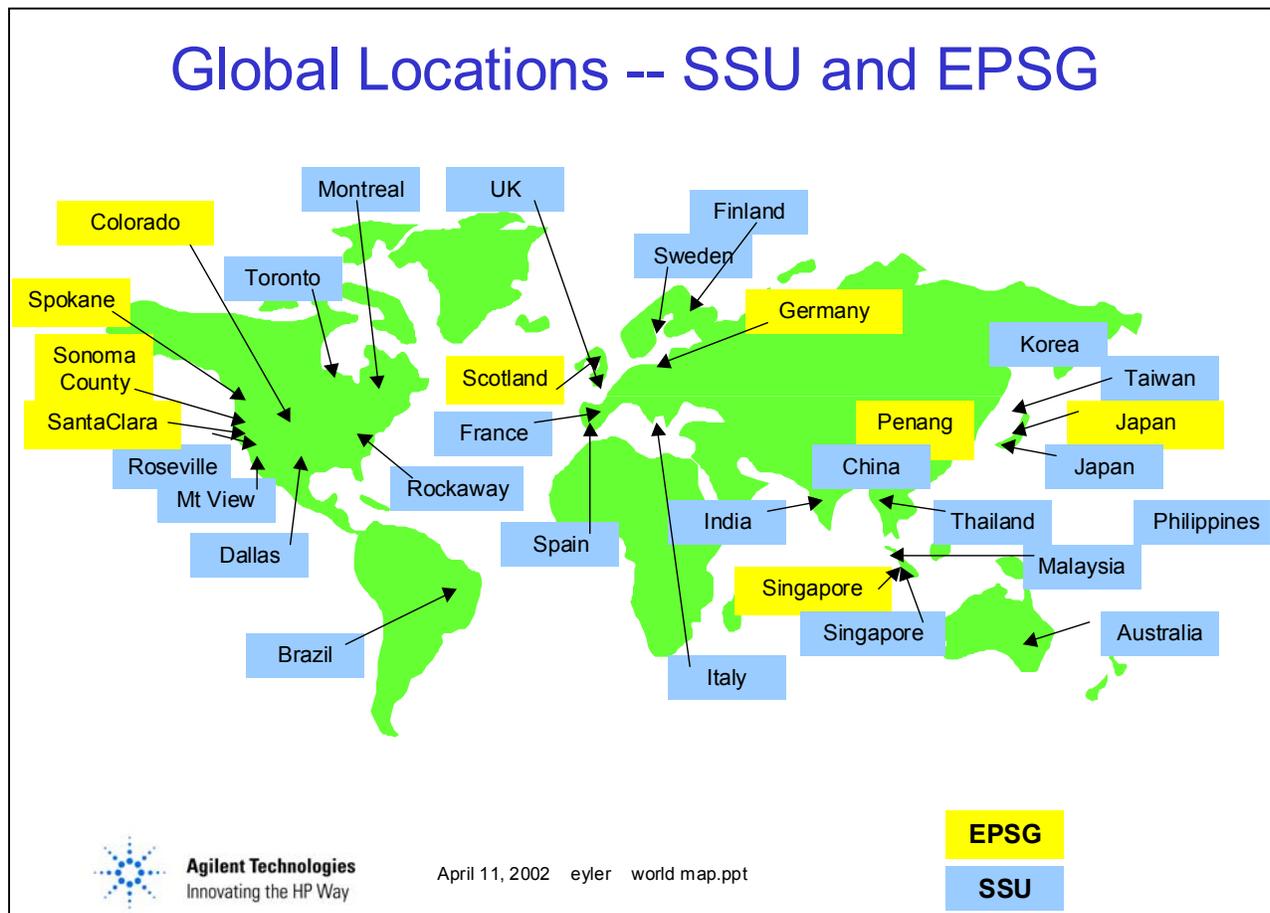


Figure 1 Selected global locations of SSU and EPSG entities

Within the SSU structure is a global support group and four regional or geographic teams. The regional teams support local service center operations and serve to implement processes and programs. The global group sets policy, designs, and develops the processes that are in turn

directed to the regional teams. The global group consists of several platform functions, one of which is the Global Quality and Metrology function. The SSU internal audit function reports to the Quality and Metrology function. This reporting structure is a relatively recent change and represents an important aspect of improving the overall audit program.

3 Internal Audit Program

The SSU internal audit program is actively administered by the SSU Audit Program Manager and is fully described by the Audit Program Description (APD) document [1]. The APD is the policy manual describing the high level processes to be followed by SSU auditors. Its purpose is to define the audit program and methods to be utilized by auditors to achieve consistency throughout SSU and other Agilent Technologies entities that choose to participate in the program. It is composed of four specific sections, the program objectives, a description of the audit program services, the audit process, and an appendix focused on selected key technical considerations. These sections are discussed in more detail as follows.

3.1 Program Objectives

The program objectives section discusses the three primary objectives of the internal audit program. It supports the desire to build consistency and establish reliable measures of business compliance to key quality standards across the SSU organization. The first objective is to meet the demands of industry related to compliance with ISO 9000 and 17025 standards. Our intent is to utilize the audit program to help achieve a high level of global consistency and help in guiding decisions for continual improvement.

The second objective is focused more internally by working with our EPSG partners to insure ongoing product specifications and customer value. To that extent, we partner with many EPSG entities to build common calibration processes and deliverables.

Finally, our third objective is designed to insure service products provided by global SSU entities are as consistent as possible and meet the requirements of the various world wide standards we adhere to in our Quality System Manual (QSM) [2].

3.2 Audit Program Services

The program services section includes detail on the activities and responsibilities of the Audit Program Manager in support of the overall audit program. Defining the types of audits, the tools used for conducting them, and scheduling the many internal and some external supplier audits is a major functional task for this position. Annual scheduling of internal audits includes reviewing past results, understanding critical needs, and balancing the funding to accomplish the objectives. Training and qualification of auditors is another very significant activity, often involving a high level of partnering with our EPSG entities. Developing audit strategies in view of changing business and customer requirements is yet another important aspect of this role. Defining and

¹ E. Tong et al, Audit Program Description, Agilent Technologies, Rev APD2001, Nov 2001

² M. Randolph, G. Burnett, D. McCarthy, et al, Quality System Manual, Agilent Technologies, Feb 2001

managing the audit records archiving process is another important role so that users of the audit records can easily access needed information.

3.3 Audit Process

This section outlines in detail the tactical processes an auditor would follow to organize, prepare, conduct, and follow up on an audit. Guidelines are offered for scheduling the audit and setting the stage with the entity involved. Detailed suggestions are provided for an opening meeting and a subsequent clear down of issues from the last audit. Guidance is given for the use of audit checklists as a method to structure selected audits. Definitions are given for the various types of nonconformities and how to handle more serious situations should they be observed. Corrective action planning is reviewed and details are included about the audit reporting process.

This section includes a process flow chart describing the overall audit process steps from recognizing an audit is scheduled to completing a final certificate. The actual audit process in the APD has been utilized for several years within SSU. It is an effective tool, particularly when used in a training situation. It is also an excellent tool to discuss with external auditors who wish to review our internal audit process in more detail.

3.4 Technical Audit Appendix

Occasionally an internal entity will require an assessment of their production processes in addition to a scheduled quality system audit. The purpose of this Appendix is to describe how the technical or production component of an audit can be most effectively accomplished. The technical portion of the audit will focus on the requirements found in section 5 of ISO/IEC 17025:1999(E) and the ANSI/NCSL Z540-1-1994 standards. The SSU Quality System Manual (QSM) describes how we comply with these standards and it has been accepted as written. The audit, therefore, may be performed against the appropriate paragraphs of the SSU QSM. Over the last several months, we have noted an increased emphasis requiring this type of technical audit to review how measurements are being performed, procedures and standards used, and how the service center is maintaining their standards and measurement systems.

Topics within the Appendix include the following:

- ◆ Entering calibration factors into test systems for equipment that requires correction factors to be utilized during calibration
- ◆ Specific considerations involving the 3458A
- ◆ Review of Out Of Tolerance events
- ◆ Power measurement considerations
- ◆ Review of testing/calibration procedures
- ◆ Verifying the calibration and deliverables of completed product

The technical audit issues that are listed above are only for information and guidance. Since all possible technical findings cannot be anticipated or explained, the auditor is free to follow-up any suspected technical problem that is identified. In many situations the auditor engages the assistance of a technical manager in performing portions of the technical audit.

3.5 Audit Program Changes

As indicated in Section 1, the audit program has been influenced and undergone change due to several factors. The factors effecting change were primarily a desire to further improve the audit program, impact of ISO 17025, and business conditions resulting from a world wide economic slowdown. The overall audit program and its reporting structure was reviewed prior to any decision to make changes. Figure 2 lists the key changes that were made over the past year.

SSU Audit Program -- Key Changes

- Partnership -- Synergy with EPSG, Resources**
- APM Reporting Structure -- Leverage for Improvement**
- ISO 17025 Impact -- New Tools, Accreditation**
- Annual Planning -- Critical few, Meeting Customer Needs**
- Audit Strategy -- Remote Audit, Cost Effectiveness**





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Figure 2 Key audit program changes.

One important enhancement to the audit program was including more of the EPSG manufacturing sites into the overall program. This effort involved training of individuals who would be focused on the audit function for those manufacturing sites. That training continues today as manufacturing production lines develop and build their capability to become registered to certain quality standards. Integrating the ability to audit, with effective results, has reduced the time required for production lines to become operational and deliver products to customers.

A key change in the audit program resulted from shifting the reporting structure of the SSU Audit Program Manager from a strategic management level to the more tactical SSU Global Quality and Metrology group. This change enabled more responsive corrective action resulting

from audit findings, to be implemented more easily into the SSU quality system. The change also reduced some task duplication and provided a much more integrated and effective manner in which to leverage improvement across the SSU organization.

Because ISO 17025 introduced elements of greater technical detail along with the need for updated audit tools, it also was a significant contributor to change in the audit program. Tools have been and are being constructed to address aspects required by the standard. These tools and their application will be subject to audit as we move forward. New audit checklists have been developed for use in assessing sites to the ISO 17025 requirements. ISO 17025, being a foundation for accredited calibration activity, has contributed to process changes at calibration sites, which of course need to be audited.

The business climate has forced significant change on the audit program, however some very positive effect has also been realized. Annual planning to establish audit schedules for SSU global operations has been improved. Today annual planning focuses on scheduling sites with the most critical production needs, specific customer situations, and a review of past audit results rather than simply assigning a regular audit interval. This approach provides the opportunity to focus our resources more effectively to sites and situations that truly need attention.

In addition, a significant change was enacted that impacted our audit strategy and methods, as discussed in the APD [³]. Due to the current critical business condition, we found it necessary to develop an audit method designed to accomplish our objectives while minimizing resource and travel requirements. This method, called Remote Audit, introduces a greater level of objectivity and scrutiny since it requires a review cycle prior to audit acceptance by the Audit Program Manager. The audits performed using this method can be accomplished utilizing the auditee's electronic records and documentation as well as local support from a designated quality representative. Either a global quality representative or the Audit Program Manager must verify the audit results. This method may be used for internal audits only, and must be supported with a physical audit at least once every three years. This method cannot be used for an initial audit of an entity or in the event that a major non-conformity is discovered or a reorganization has occurred. It is expected that this method will be utilized on an interim basis until business conditions improve.

4 Overall Results

One important result achieved from the audit program changes was closer alignment and synergy between the SSU and EPSG entities. Another positive result, is that EPSG would like to participate in our audit program by providing some shared resources to assist with auditing in selected areas and geographies.

The reporting structure change for the Audit Program Manager has resulted in additional resources to assist with planning and audit activities. It has provided the opportunity to more effectively initiate improvement activity, with less duplication of effort, as a result of audit findings. It also presented the ability to leverage the SSU global Quality and Metrology team

³ E. Tong et al, Audit Program Description, Agilent Technologies, Rev APD2001, pp 11,12, Nov 2001

activities. This structural alignment also has been shown to be beneficial when performing technical audits or assessments to ISO 17025.

The estimated expense savings in administering the audit program this fiscal year is 60% less than the running rate over the last few years. This is due in large part to better planning, multiple audits during a single trip, and implementing the remote audit strategy.

5 Conclusions

As with significant changes in any program it was necessary to keep management informed of decisions, activities, and issues surrounding the audit program changes. Careful review and updating of existing program documentation was necessary in view of the new audit checklists. We have benefited from closer alignment with our EPSG partners, not only in resource sharing, but also better planning to support ISO 17025 calibration delivery from both SSU and EPSG sites. Annual planning has been improved and now consumes less overall time to develop audit schedules. The remote audit method is expected to be utilized whenever tight expense controls are in place. It will take on less significance as economic conditions improve.

Overall, we feel very positive about the changes that have been enacted in the SSU audit program. They have produced cost savings and provided leverage for resources and continual improvement activities.

References

1. International Organization for Standardization. *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*, ISO, Geneva, Switzerland, 1999, p.14.
2. SSU Audit Program Description, Agilent Technologies, Rev APD2001, Nov 2001.
3. SSU Quality System Manual, Agilent Technologies, Feb 2001.
4. Kerry Gwin, Quality Consultant, correspondence, Agilent Technologies, March/April 2002.
5. Ed Tong, Quality Consultant, correspondence, Agilent Technologies, April 2002.