AGA White Paper:

Developing and Implementing a Quality Assurance Program for Natural Gas Operations

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AGA Distribution Construction and Maintenance Committee - Quality Management Task Group

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I. INTRODUCTION

As a natural gas utility's top priority, pipeline safety directs how procedures and practices are developed and implemented. Safety assurance is dependent on the quality of the work resulting from carrying out those procedures and practices. The need to ensure quality has led many natural gas utilities to create quality management programs. Historically, "quality management" has been mostly associated with industries that have manufacturing processes. However, over the last decade, many natural gas utilities and pipeline operators have placed greater emphasis on pursuing more comprehensive and effective quality management programs.

A quality management program is distinct from and addresses more than merely inspecting work to ensure compliance with federal and state regulations for pipeline safety. A quality management program typically:

- Ensures that Voice of the Customer (VOC) is understood
- Ensures quality is planned
- Defines quality control activities
- Defines quality assurance activities
- Provides closed loop verification that all requirements are met

Furthermore, quality management provides an opportunity for continuous improvement of operations activities and the processes that drive those activities. Well run programs will be documented, procedures and practices will be reviewed to identify areas of improvement, and action plans will be implemented. When the design and implementation of the quality management program is focused on internal and external stakeholder requirements, the program supports and drives process improvements that ultimately drive efficiency and effectiveness.

A quality management program requires the support of top management. This support is especially crucial during implementation of a new program where organizational change management strategies may be employed and a project sponsor from top management is needed.

The need to implement permanent change to the culture which may be associated with such endeavors should not be under estimated. A compliance-driven culture, where inspection and maintenance are "have-tos," can cloud the intent and benefits of a customer-focused continuous improvement model of a Quality Management System.

II. PURPOSE AND SCOPE

The purpose of this document is to provide guidance on how to develop a Quality Assurance (QA) program for companies engaged in natural gas operations. It is not intended to provide guidance on developing a Quality Management System (QMS), which is a much broader task that would include all facets of quality control and QA, and cover all operational areas that contribute to the installation and maintenance of the natural gas pipeline[1]. However, certain elements of a QMS as described in ISO 9001 "Quality Management System -Requirements" are important characteristics of a QA program and these are incorporated into this guidance document.

A QA program refers to the activities providing confidence that the internal processes (including the Quality Control/Inspection process) are adequate, effective, and ensure safe, reliable and uninterrupted gas delivery. QA activities are focused on process conformance with regulations, internal procedures and standards, and on detecting and correcting process nonconformities. From

[1] Pipeline means all parts of those physical facilities through which gas moves in transportation, including pipe, valves, and other appurtenance attached to pipe, compressor units, metering stations, regulator stations, delivery stations, holders, and fabricated assemblies (49 CFR 192.3)

the QA activities, processes improvement initiatives are created which aim to prevent construction, maintenance or repair defects in the field. A QA program encompasses quality audits and reporting, tracking and analyzing the audit findings and subsequent corrections and corrective actions. It does not include the routine or daily inspections of construction needed for "fitness for use," such as those inspections required by various sections of 49 CFR 192 and CSA Z662; these are considered Quality Control (QC)[2].

QC activities are implemented to fulfill quality requirements. Having trained and qualified personnel to perform work; having written procedures to do the work; and inspecting product conformance against drawings, specifications, and technical regulations, in order to identify and correct manufacturing, construction, maintenance and repair defects are all aspects of quality control. As mentioned above, inspections required by federal regulations on pipe and components, plastic pipe joints, welds, and steel pipe coatings before a pipeline is put into service are examples of quality control. Another example is performing inspections and tests of purchased materials to verify if they meet design and purchase specifications. By detecting and addressing manufacturing, construction, maintenance or repair defects after they occurred, but before turning the gas on, they may prevent near misses or incidents.

While this paper focuses on integration of quality management principles into a gas operations QA program, the concepts presented are equally applicable for QA of contractors working on behalf of the operator in any capacity, including construction and maintenance activities

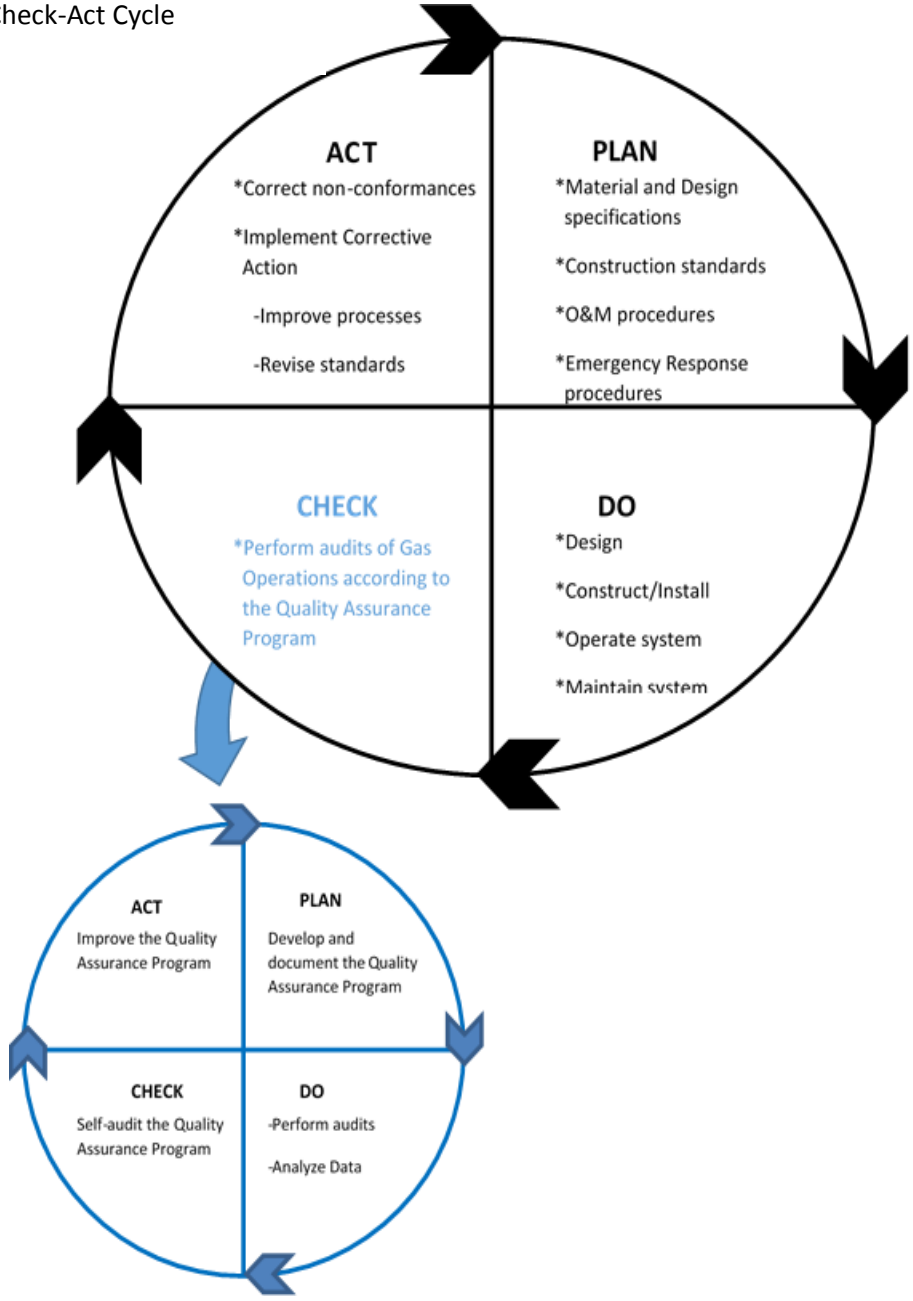
III. PLAN – DO – CHECK – ACT

A simple way to consider the implementation of quality management principles for gas operations is through the continuous improvement cycle of Plan-Do-Check-Act (P-D-C-A), with the QA function serving as the "Check" and driving the "Act" portions of the cycle. By thinking of the operations activities in this manner, the result will be improvements in both operational processes and the outcomes of those processes. The operations processes include company policies and procedures as well as individual business unit processes. Examples of process outputs include the actual gas pipeline infrastructure, operations or maintenance activity on the pipeline, and the records of the construction, operations or maintenance activities.

Similarly, viewing the QA program itself through the P-D-C-A lens will help operators design and implement a quality management program that will also continue to improve. The P-D-C-A concept for gas operations, as well as for the quality assurance QA program itself, is illustrated in Figure 1 below.

[2] In this paper, references to QA and QC are meant as elements of a QMS, and not as departments within a company. In many companies the QC department might perform QA audits while the QC function might be performed by Field Inspectors.

Figure 1: Plan-Do-Check-Act Cycle



The "Plan" refers to the design and construction standards and specifications, along with operating, maintenance and emergency response standards and procedures required by federal regulations 49 CFR192.605[3]. These are documented in an operator's standards and procedures manuals.

What an operator might currently not have formally documented are the processes that support conformance with those standards and procedures. While not the topic of this paper, operators should consider creating written business processes of the activities that are followed in order to meet what is

[3] 49 CFR 192.605 applies to gas utilities within the United States only, for Canadian reference review CSA Z662.

in their design, construction and O&M manuals. Documented processes improve consistency in application, assist in training of new personnel, and support business continuity and knowledge management.

The "Do" portion of the P-D-C-A cycle for gas operations is performing construction, operations, maintenance and emergency response activities as required by the "Plan". (Note: Design is also listed in the "Do" section of the P-D-C-A figure as individual operators may choose to include design in their quality management program as noted below.)

The "Check" element of the P-D-C-A cycle is where QA activities take root. Monitoring, measuring, analyzing, and evaluating construction, operations, maintenance and emergency response processes, incident investigation procedures and corresponding "products" will help identify opportunities for improvement. These process improvement ideas form the basis for action plans – the "Act" part of P-D-C-A. Design activities and purchasing of material and components may not be viewed as 'gas operations'; however, they are major factors in the overall quality of an operator's gas pipeline infrastructure and part of the broader 'product realization life cycle'. Hence, these activities may be included in the scope of QA program.

This paper provides guidance for operators on the development and implementation of a QA program that embodies the monitoring and measurement activities (the "Check") and the corrective action activities (the "Act") necessary for continuous improvement. Documenting and carrying out a plan that covers these components completes the P-D-C-A loop for operators.

IV. DEVELOP AND DOCUMENT THE QA PROGRAM ("PLAN")

To implement any program, careful thought must be given to the design and development. The majority of this paper is devoted to the development of a QA program which would be documented in the form of a written QA plan. This is the 'Plan' portion of the smaller P–D-C-A loop shown in Figure 1 above. Developing the QA plan begins with identifying and understanding who is considered a stakeholder of the QA program because this is essential to building a strong foundation for a success. The needs and expectations of the program's stakeholders influence everything in the QA plan from the objectives and scope to reporting and corrective action.

The following sections provide information for consideration of how to create a QA program plan as a means of measuring performance against requirements and using the information to drive improvement in gas operations. The objectives, scope, roles and responsibilities, and qualification and training of the individuals carrying out the QA program should be documented in an overall QA plan. The QA plan would also describe the audits that are covered by the program, and any business processes, including reporting and corrective action policies.

A. Objectives of QA Program

Early in the design phase, the objectives of the QA program should be clearly defined. Objectives should link to your company's corporate strategies and as such, will be unique to each operator. Quality objectives ***could include***:

- Ensure adherence to federal, state or provincial, municipal and company standards
- Reduce the possibility of pipeline incidents
- Measure system and worker performance
- Evaluate the transfer and effectiveness of training
- Improve customer service
- Evaluate the effectiveness of business processes

- Identify areas for process improvement
- Validate quality of materials and services provided

B. Scope of QA Program

The scope establishes the boundaries of the program – therefore, it is essential that the operational functions that will be included in the program be identified and documented. Consideration should be given to the maturity of the program and available resources – if the program is new, a smaller scope may be warranted and the program can expand over time. For example, a program with a smaller scope may begin with construction activities and over time will phase in other activities. When establishing an initial scope, a risk-based approach can be utilized to prioritize the areas for implementation. Generally, gas utility QA programs focus on one or more of the following areas that comprise the universe of gas operations work:

- Construction – including, but not limited to:
    - New construction
    - Conversions
    - Main extensions
    - Relocations
    - Cut offs
    - Replacements
- Operations activities – including, but not limited to:
    - Odorization
    - Control room management
    - Continuing surveillance
    - Damage prevention (e.g., locates, standbys, etc.)
    - Corrosion control
- Maintenance activities – including, but not limited to:
    - District regulator stroke and lock-up
    - Meter work
    - Valve maintenance
    - Patrolling
    - Pipeline marker maintenance
    - Atmospheric corrosion monitoring
    - Leakage activities (e.g., surveys, leak re-checks, etc.)
- Emergency response (e.g. odor calls, line break repair, etc.)

Some programs may also cover a broader spectrum of the overall operations life cycle including:

- Materials
- Design
- Customer field services activities, such as service calls, appliance maintenance, etc.

Another consideration is any commitment made to the operator's regulatory agencies, for they too are stakeholders of the quality management program. Such commitments may add to the scope of the program and have an impact on one or more audits that are performed.

Defining the program's scope will help determine the staffing levels and department structure needed for the quality management program to succeed.

C. Roles and Responsibilities

Roles and responsibilities should be defined for each position within the QA program. Job titles generally reflect the responsibilities of the position but individual company human resources policies may also drive the position names.

Defining each role and set of responsibilities requires consideration of how the role will communicate, cooperate, and plan activities with other departments. In addition, required skill sets for each role should be reviewed while defining roles and responsibilities. Some of the roles and responsibilities that require special skills include, but are not limited to:

- Audit plan development and reporting
- Root cause analysis
- Trend analysis
- Conducting audits

It is important to delineate the difference in roles and responsibilities between the QA personnel that are serving a QA function and the roles and responsibilities of inspectors that are fulfilling the quality control inspection requirements in 49 CFR 192[4]. In addition, the roles and responsibilities of other operations personnel in fulfilling the overall quality plan should be determined and documented.

D. Qualifications of QA Program Personnel

After roles and responsibilities for the QA program personnel are defined, required qualifications must be determined and documented in the quality plan, so that competency can be measured. Aligning the qualifications to the responsibilities is an important step in assuring employees with the right skills are utilized for carrying out the QA program. Consideration should be given to the following:

- The type of audits that will be performed (See next section)
- The level of construction and/or operations experience needed
- The level of quality management knowledge needed
- Special certifications needed (e.g., Certified Quality Auditor and/or Six Sigma Certification)

Qualification of QA personnel is not intended to imply that these employees need to be Operator Qualified according to the Operator Qualifications (OQ) regulations (per 49 CFR192).

E. Develop and Document Quality Audit Procedures

At the heart of the QA program are the audit procedures. The procedures describe the what, when, who and how related to monitoring and measuring performance against requirements. In developing the procedures, it is important to know who your stakeholders are and the requirements or expectations they have of the program. It is also critical to identify the requirements that form the basis for the monitoring and measurement and to determine the audit types that will be used. The QA program audits will indirectly evaluate the effectiveness of training and OQ programs, while also identifying areas for future training and/or OQ changes.

[4] 49 CFR 192 applies to gas utilities within the United States only, for Canadian reference review CSA Z662.

There are also instances where a direct evaluation of training effectiveness is needed. Therefore, quality audits should be aligned with the training curriculum and Operator Qualification program.

A common approach is to develop a menu of standard, or routine, audits for work included in the scope of the QA program. These standard audits are performed on some recurring basis, depending on the frequency established. For many companies, these routine audits may make up the majority of the QA audits they perform.

However, not all audits will be pre-established. In addition to the routine audits mentioned above, there are many inputs that may drive the initiation of another type of audit. In these cases, a specific audit plan is prepared and the audit is usually a one-time event. There are a number of terms that operators use for this type of audit, such as targeted, focused, and ad-hoc. Typical inputs that would trigger this type of audit include:

- A high error rate of a specific item on a routine QA audit. For example, construction as-built records showing a high rate of non-conformance might drive a specific audit of as-built records generated by a particular employee, or crew, or region might be performed.
- Results from data analysis. For example, comparing technician leak discovery rates for a particular pipe material and installation dates. Technicians who fall outside of the average leak discovery rate for both high and low could become targeted for a procedural audit.
- Incident investigations (i.e., a "for-cause" audit triggered by an event or finding)
- Newly qualified employees. A process audit focused on one or more tasks the new employee is required to perform could be done to assess the effectiveness of the employee's training and/or their level of performance/competence.
- Regulatory orders (e.g., a mandate from the operator's state or province utility commission)
- Business unit direction (i.e., customer request)
- Special projects
- Safety alerts/advisory bulletins
- Policy changes. Some changes to the operator's O&M manual might include requirements that would not ever get assessed through a routine audit. For example, a special form or a notification that is required to be made under certain conditions in the field where only a special audit would be able to determine if the policy is being followed and to establish if training on the policy change was effective.
- Compliance (e.g., regulatory change that results in a new program or requirement)

In all cases, audit procedures should be documented using a document control system[5]. The procedures should define:

- The purpose of the audit – why the audit is being performed
- The scope of the audit – this includes the entity (work group, contractor, organization, etc.), the work/activity/record that is being audited and the time frame for the work/activity/record
- The audit method, including how the audit is to be carried out, how the samples will be obtained and the checklist for the audit
- The source of the requirements (e.g., standards, procedures, or other reference documents)

[5] See Section IV. H.

- The type of audit (product or process)
- The frequency of the audit (audit cycle)
- The sampling methodology that will be used
- The sample size
- Tools and instruments that are required to do the audit
- Safety considerations for the QA personnel doing the audit
- Recording and reporting on audit findings, including communicating audit findings to the appropriate parties

The following sections provide more detail on some of the audit procedure elements listed above:

1. Identifying requirements - For gas operations, requirements are generally embodied in the operator's standards and procedures manuals, O&M manuals, etc. Depending on the scope of the QA program, there may be other documents, such as material and design specifications, that contain requirements.

   The requirements form the basis of the checklists which are a critical component of the audit procedure. In developing the audit checklist, items that should be verified (as applicable) include;

   - Compliance with relevant laws and regulations
   - Conformance with Company policies, plans, procedures
   - Records integrity (completeness and accuracy)
   - Records retention
   - Timeliness;
   - Compliance deadlines
   - Qualifications/training of the personnel performing the work
   - Required actions of the personnel performing the work
   - Testing/calibration of equipment used in performing the work

   As requirements change, either through regulatory revisions or company policy changes, it is imperative to update the audit procedures and checklists to reflect these changes.

2. Determining audit types – Audits can be categorized into three types: product, process and system. This paper will focus on product and process audits which are typical of QA programs covering gas operations. In developing the audit procedures for the QA program, understanding, identifying and documenting the audit type will aid in determining other important components of the audit procedure such as the sampling method, obtaining the audit samples, and the audit method. (Refer to sub-sections 4 and 5 below).

   Product audits (e.g., audits of a new main or service installation or an audit of the records of an operations or maintenance activity) are very common because the audit can be performed after the work activity is completed and they are relatively simple to perform.

   Audits of processes, such as fusion, welding, or valve maintenance are typically performed directly by auditing each step of a process as it is being performed. It is also possible to indirectly audit a process by doing an audit of the product of the process. For example, a records audit may reveal inconsistencies in the process used in different areas or a deficiency in the process of completing the record and getting it to the location where it is to be filed.

3. Establishing audit cycle – Determining how often a particular audit will be performed is important so this information can be communicated to the auditees, as well as to the stakeholders of the QA program. Some audits may be performed monthly, others one time per year, and still others may be on a multi-year cycle. Factors to consider in establishing the audit cycle, or frequency, include the following:
    - Risk level of items covered in audit
    - Frequency of the activity being audited
    - Performance level established through a prior audit
    - Regulatory requirements
    - Industry Standards[6]

4. Audit samples – The components related to sampling include the sampling methodology and sample size determination. The sampling methodology refers to whether samples are selected randomly from the population of work or if there is some strategy into which work or records are audited. The scope of the audit (who, what, when) will have a big influence on the sampling method because selecting a random sample from a known population of work may not always be possible for a particular audit. The population of work is often established by determining the number of 'jobs' performed during the audit cycle in a particular region or by a particular employee, department, or contractor.

    For sample size (i.e., how much is audited), many operators default to auditing a certain percentage of the work. However, this approach may not provide the greatest value because it does not guarantee that the right amount of the right work is being audited in order to ensure improvements are focused where most needed. Operators should consider the following factors when establishing the sample size:

    - Risk level (of work being audited)
    - Past performance (high performance warrants less sampling)
    - Population of work – the operator may choose to sample from a population based on work types, operating areas, crews, or employees. The population breakdown will influence how much is looked at.

    There are many resources available to help with determining sampling methodology and sample size determination[7].

5. Audit method – The audit method has to do with how the audit is performed. The audit procedure should establish whether the audit is in the field or office. It should also cover how the samples are obtained and how the objective evidence is gathered. If construction activities are within the scope of the program, then typically a field audit of the installation would be an integral component of the program. Field audits may be performed with the crew on site or post-construction. In an on-site audit both product and process audits can be performed; with a post-construction audit the focus is on the product.

    One benefit of conducting field audits of construction with the crew on site is that requirements such as cover and underground clearance can be measured (i.e., a product audit). Also, tasks such as fusion or welding could be observed and measured against the procedure requirements (i.e., a process audit). Audits

[6] API 1173 requires each process to be audited at least once every three years

[7] See Appendix A for some sample resources. The sample resources in Appendix A do not represent a comprehensive list.

performed after construction (post-audit) are useful in gathering evidence on the conformance of the completed work but may necessitate excavation of buried pipe in order to assess certain items on the checklist. A program that includes both onsite and post audits will provide a more complete and holistic picture of the level of compliance/conformance of the work being performed.

Note: Many operators refer to the field aspect of their QA program as a "field inspection". It is worth distinguishing between an inspection and an audit. An audit of gas pipeline construction is similar to an inspection except with an audit there is always a level of independence from the work being performed and the results of the audit are not used to approve putting the pipeline into service. As noted earlier, an inspection is considered a quality control activity and an audit is a QA activity. Furthermore, the inspection requirements in 49 CFR 192 and CSA Z662 are required to be done on every applicable installation. An audit will almost always only sample a portion of the work and, as noted for a construction audit, could be done after construction is completed and there is no crew on site.

For O&M work, field audits may also be performed if an operator wants to assess O&M procedures while they are being performed by operations personnel. Examples of these procedures would include odor call response, leak surveying, atmospheric corrosion monitoring, pipeline locating, and system operations (e.g. pressure control and corrosion control).

Other audits can be done without going in the field. These types of audits are usually of construction records, such as as-builts, or of O&M records, such as leak records, exposed pipe condition reports, valve maintenance records.

The process for obtaining the samples is simply a description of where to go, who to talk to, or what database/system to access to get to the information so the samples can be selected. For instance, for construction work, a crew list with job addresses, real-time access to dispatch and GPS location information or a download from a work management system may be utilized. Similarly, for O&M records, the procedure would describe where the records are located. The process for obtaining the samples will be unique to each audit.

6. Tools and instruments –The tools or instruments necessary for QA personnel to perform the audit should be identified and documented in the audit procedures.

7. Safety considerations – Depending on the location where the audit is carried out, personal protective equipment (PPE) may be required. There may be other safety considerations for the person performing the audit. This information is appropriate to include in an audit procedure so that QA personnel safety is not overlooked.

8. Recording and reporting audit findings –The individual audit procedures should state how the particular audit findings will be recorded and should also include key aspects of reporting the findings, such as the method of delivery (e.g., e-mail), the format (e.g., a report form or template), and the recipients of the report. See section F below for more information on recording and reporting

In addition to specific audit procedures, business processes that govern the overall audit process should be developed. The intent of these processes is to establish the customer service that will be provided to the gas operations groups that are subject to

the audit (e.g., process for contesting findings, focused/targeted audits, including communication and timelines).

A process flow diagram is also a useful tool to capture the audit process from beginning to end and can complement the business process documents.

F. Recording and Reporting

The QA program business processes should establish the methods, forms and templates for recording and reporting audit results. The purpose of recording is to be able to identify trends and progress, to determine if action needs to be taken, and to give visibility to critical versus minor non conformances. The audit data is considered the "objective evidence" that ultimately supports the information provided on audit reports. Typical methods of recording the data collected during the audit include the following:

- Hard copy checklist forms
- Electronic spreadsheets
- Electronic databases

A method to track audits should be established. Typically, a tracking number is assigned to each audit following a numbering protocol established by the QA personnel. For each unique audit, the following information might be tracked:

- Quality Auditor name
- Audit status (such as open, in progress, or closed)
- Date audit started
- Date data gathering is completed
- Date report is completed and distributed
- Dates of kick-off meetings and closing meetings, if applicable
- Date CAR is issued[8]

The audit report is the product of the QA program. As such, reports need to fact based, accurate, concise and clear. The purpose of reporting is to communicate to those with authority to take necessary action and to communicate relevance and value to upper management. The opportunities for reporting audit findings include, but are not limited to:

- Reporting on the individual sample (e.g., an individual job for main or service installation),
- Reporting on an audit (e.g., a collection of samples in a specific area), and
- Summary reporting on all audits collectively

The objective, scope and stakeholders of the QA program will all influence the method, frequency and format of the audit reporting.

To provide consistency in report format and efficiency in generating reports, operators should consider developing report templates. Templates can be used for all types of reporting. Individual construction audit samples (i.e., each audit) may be reported by simply sharing with appropriate stakeholders the individual checklist items and any non-conformities that were corrected or that require correction.

[8] See Section IV. G.

Summary reports of the overall QA program may include the total number of samples in the audit, a summary of the total non-conformities, and/or trends across all audit samples over the reporting time period.

For recurring audits that may be performed on an annual cycle, or for special audits, a more formal report that includes some or all of the following is considered standard:

- Introduction/background
- Objective
- Scope
- Audit summary/findings
- Positive practices
- Observations
- Conclusion
- Required corrections
- Request for corrective action

Distribution of QA audit reports should be determined. The report distribution process must include both to whom reports are provided and the report timeliness (i.e., how soon after completing the data gathering are reports are finalized and distributed). For routine type audits, it is common practice to provide results of the audit the same day or within one business day, depending on the technology the operator uses. The results may be considered a "field report" of an individual sample of work with a more formal summary reporting provided to appropriate stakeholders and auditees at a later date.

Other considerations when developing reporting processes and protocols for the QA program include:

1. Reporting observations to cover the following situations:
    - Where something is obviously wrong but cannot be recorded as a nonconformity because it does not contravene the words of regulation or procedure.
    - Where the situation does not justify a nonconformity, but is likely to deteriorate if no action is taken
    - An opportunity for improvement is identified
2. Discussing audit findings (e.g., particularly nonconformities) with the auditees at the time of the audit, so the official audit report should include no surprises.
3. Communicating process and time frame if audit findings will be contested.
4. Referencing the regulation or internal procedure related to each non-conformity.
5. Prioritizing nonconformities based on frequency (isolated case vs. systemic), criticality (low impact vs. catastrophic consequences) and emergency (can wait vs. must fix now). Note: "Frequency" should be calculated as a percentage of how many times a specific item was a non-conformance in relation to how many times the item was audited, rather than a simple count of the occurrences.

It is important to emphasize that QA reports must be used in a constructive and not in a punitive manner. The goal is to identify nonconformities, correct them and prevent their reoccurrence.

G. **Corrections/Corrective Action for Non-Conformances**

The QA program should provide written guidelines on how audit findings will be handled, when corrective action should be initiated, and the process for working with stakeholders on developing and documenting a corrective action plan. The corrective action process is ultimately what drives the continuous process improvement in gas operations and assures the quality necessary to meet requirements.

Corrections and corrective actions are both important methods of dealing with non-conformances but serve different purposes and may not be required in all cases. A correction, also considered "remediation", simply fixes an individual non-conformance that is found during a quality audit. On the other hand, corrective action involves completing tasks that will prevent recurrence of an identified non-conformance. Corrective actions should be designed to address the root cause of the problem.

Typical ***corrections*** include:

- Rework (e.g., lowering a service, replacing a connection, adding backfill)
- Correction of data on a form or in database

There are many approaches to requesting correction of a particular non-conformance, depending on the audit. Some operators include the requirement on a field report for the construction audit; some operators issue separate forms (e.g. "Notice of Exception"); and in some cases, the requirement may be part of a larger corrective action plan.

Typical ***corrective actions*** include:

- Revision of existing process
- Development and implementation of a new process
- Development and implementation of tracking spreadsheets or databases
- New forms or revisions of existing forms
- Training of employees
- Revision of company standards or procedures

Corrective Action Plans (aka CAP or CAPA) should be documented using a method established by the QA personnel with input from the stakeholders of the QA program. A simple method is to use a form to capture key information about the why, what and when associated with the corrective action along with management approval to demonstrate buy-in of, and commitment to, the action plan. Such forms are typically referred to as a Corrective Action Request or Corrective Action Report (CAR) and would capture the following information at a minimum:

- Action owner
- Clear action item(s) to address the findings with deadlines for completion
- Required evidence that demonstrates completion of the action item
- Corrections that will be made, if applicable
- Management approval of the action plan

To round out the corrective action process, operators should consider the following:

- Tracking of required corrections. The system used for recording audit findings should be able to capture and track this information.
- Tracking of corrective action plans. Common methods are to assign numbers to CARs and use a spreadsheet and/or databases to track the status of open action items.

- Establishing and documenting criteria for what makes a good action plan in order to facilitate the creation of a value-added plan.

The final element in developing the correction and corrective action processes for the QA program is the verification policy. Verification is simply an independent validation (based upon objective evidence) that corrections were made and corrective action items were completed. Consideration should be given to:

- Will each correction be verified? If not each, what type will or will not be verified?
- Who will perform verifications? Can anyone on the QA program staff perform the verification or only the person that performed the audit?
- How will verifications be performed? For field remediation, will QA personnel go back to the field or will the person performing the correction be allowed to submit photo evidence or will a field supervisor be able to sign off?
- How will verification be documented?

In the case of individual action items in a Corrective Action Plan, verification of each action is an important follow-up activity required to close an open action item. However, in the case with remediation of individual non-conformances, verification of each remedial action may not be necessary. The maturity of program, the type of non-conformance, and the history of completing the corrections may dictate how and how much the QA program personnel verify.

H. Document and Records Control

It is highly beneficial to establish a document control procedure for the audit procedures, business processes, forms and templates used for the QA program. Document control simply involves establishing a protocol for:

- Approval of documents for adequacy prior to issuing for use
- Review, update, and re-approval of documents
- Ensuring changes and the current revision status of documents are identified
- Ensuring relevant versions of applicable documents are available for use by QA personnel
- Ensuring documents are clearly labeled and identifiable (e.g., title, date, author, and/or reference number)
- Ensuring documents of external origin that are determined to be necessary for the QA program are identified and their distribution controlled
- Preventing unintended use of obsolete documents, and application of appropriate identification to them if they are retained for any purpose

Control of the records generated through the audit process is also important to establish. This would include, but is not limited to, audit reports, completed checklists and other working papers, and forms used to document corrections and corrective actions (see Section X). A robust QA program would have a written procedure that covers the following information related to records:

- Identification

- Storage
- Protection
- Retrieval
- Retention
- Disposal

V. IMPLEMENT THE QA PROGRAM ("DO")

Once the QA program has been planned and documented, QA personnel will be able to carry out the program according to the plan. This is the "Do" portion of the P-D-C-A cycle for the QA program. The following information is intended to provide considerations during implementation of the program.

A. Training QA Program Personnel

Just as training and OQ is essential for operations employees performing construction, operations, maintenance and emergency response tasks, so is having and implementing a training plan for employees carrying out the QA program. Consideration should be given to the following:

- Who will do the training?
- How long of a training period is needed for proficiency?
- What ongoing training is needed and what is the frequency?
- What external training is needed?
- How will training be performed when requirements used to govern audit checklists change?

External professional groups can help guide a comprehensive training program. Some groups that assist in development are regional gas associations or the American Society for Quality (ASQ).

A QA training (or competency) matrix is a tool that can be used to document the required competencies for the position. This can then be used as a way to compare the requirements to the skill level of the employees performing the roles. This gap analysis helps determine where the quality management program personnel have critical training needs and can be used as a tool for managing people development.

1. <u>Performing, Recording and Reporting QA Audits</u>

In implementing the QA program, it is important to view the audit process as simply collecting data. This data, in the form of objective evidence of whether requirements have been met, is then available for analysis and the analysis provides knowledge that drives improvements.

For process audits, the auditor should develop a basic technical understanding of the activity that will be assessed. This understanding includes knowing the process steps and the areas of groups involved in those steps. One way to become knowledgeable in the activity is to create a flowchart or map the process. Additional understanding may be obtained by reading reports of prior audits for that area, reviewing applicable working papers, researching associated literature and holding discussions with management inside of the area or function to be audited.

Once an audit is performed, it should be documented as quickly as possible so the information is available for analysis and reporting. As soon as practical after the audit is complete, the information would be entered into the system established for the QA

program[9]. A common practice is to allow departments the opportunity to review and contest before information is finalized.

Results from audits are used to:

- Identify trends and potential risks.
- Pinpoint the need for root cause analysis. Different nonconformities may have the same root cause.
- Identify opportunities for improvements.
- Identify where standards should be updated or clarified.
- Identify skill gaps and inconsistences that can be used to improve training and Operator Qualification (OQ) tasks.

Reporting on findings generally takes place on two levels – individual audit reports and summary reports. QA reports (a summary of QA audit results) are a crucial element of the management reviews. Trends and patterns should be identified and used to validate whether the previously completed corrective actions have been adequate and efficient.

2. Corrections, Corrective Action and Verification

Corrections are typically made as the non-conformance is found and reported upon. If there are a lot of similar non-conformances it may lead into further corrective action[10].

In determining whether corrective action is needed, the risk of the finding should be considered. Questions that might be addressed are:

- Is there a high consequence from the non-conformance?
- What is the likelihood of the non-conformance leading to a failure or an incident?
- Is there a high number of non-conformances (or is the non-conformance an isolated case)?

The written Corrective Action Plan should be directed at issues that were addressed in the audit; new, unrelated areas of concern should not be introduced. Ideally, the corrective action is aimed at the root cause of the issue. Due dates for corrective actions and subsequent follow up audits might vary considerably.

In general, corrective actions fall under one of these three categories:

- The necessary corrective action is known and can be taken right away, with minimum effort and resources.
- The necessary corrective action is known but requires significant efforts and resources (e.g., a Project Manager is required to coordinate these efforts).
- The necessary corrective action is not known, therefore a root cause analysis (RCA) is needed and special skill sets (e.g., Six Sigma specialist) is required to identify the solution.

Management should prioritize resources in taking corrective actions, based on cost benefit analysis and all risks associated with not taking timely corrective actions to eliminate the root causes. In some cases, preventive action may also be implemented.

[9] Refer to Section IV. F.
[10] Refer to Section IV. G.

Preventive action requires that you have an idea of what might happen, such as knowing an area is a risk but it has never had an occurrence of non-conformance.

For both corrections and corrective actions, perform and document the necessary verification of the action taken as determined by the policy established during the design of the QA program.

VI. AUDIT AND IMPROVE THE PROGRAM ("CHECK-ACT")

While the purpose of the QA program is to measure the performance of gas operations against requirements and drive continuous improvement, the QA program itself needs to be checked and improved. This action completes the P-D-C-A loop as it relates to the QA program.

One way to accomplish this is through a self-audit to determine the effectiveness and efficiency of the program. In addition, effective and efficient processes are the direct result of meeting customer needs and expectations, so to further drive improvement in the program, customer satisfaction should be measured collecting feedback from the stakeholders of the QA program, measuring customer satisfaction and making changes as a result helps the operator provide stakeholders with the best in class service and product quality.

Through a self-audit and customer feedback, the following questions should be answered:

- Is overall operations performance improving over time?
- Are the audits driving continuous improvement?
- Do the audit frequencies, sample method(s) or sample sizes need to be revised?
- Do quality management program performance metrics (such as audit cycle time) need to be created or revised?
- Are the stakeholders served by the quality management program satisfied with the information and how it is presented?
- Should the scope of the program change?
- Is the training of the QA program personnel effective?

Another option for assessing the quality management program effectiveness is to have an audit performed on the program by your Company's Internal Audit department or a third party.

Findings from the self-audit or external audit of the quality management program generate continuous improvement of the program itself and keep the program relevant and value added. Improvements may include:

- New or revised business processes for the quality personnel
- New or revised audit procedures
- Revised report formats, delivery methods and frequency

As program matures, tools such as Lean and Six Sigma may provide methods for process improvement.

VII. CONCLUSION

The simple concept of the P-D-C-A cycle provides a framework for operators to develop, implement and continuously improve a QA program. An efficient and effective QA program integrated into gas operations will provide the checks needed to drive continuous

improvement in the gas operations processes and the outcomes of those processes. As a service function, it is essential to know the QA program stakeholders and their requirements, and to build relationships in order to deliver effective results. The program itself is driven by the operator's strategic goals and the depth and breadth desired of the QA program.

Planning the QA program includes the development of the processes and procedures that the program personnel will follow. Documenting the processes and procedures supports efficiency in training of program personnel, consistency in carrying out the program, and program continuity. It takes time to build a program and, when setting up a brand new program, the scope of the program should be carefully determined to ensure the program is successful at meeting the desired objectives. After implementing and operating the program (the "Do"), self-assessing and improving the program will complete the P-D-C-A loop. Repetition of the P-D-C-A cycle leads to program maturity and may also result in expansion of the scope of the program.

There are many resources available to operators to support the development and continuous improvement of a QA program used in natural gas operations. Appendix A provides a short list of organizations, publications and websites as a starting point for personnel new to the quality environment as well as those that may currently be carrying out an existing QA program.

Appendix A – Resources

1. American Society for Quality – asq.org
2. ANSI/ASQ Z1.4-200X Sampling Procedures for Inspection by Attributes
3. ISO 9000-2005 Quality management systems – Fundamentals and vocabulary
4. ISO 9001-2008 Quality management systems - Requirements
5. ISO/TS 29001 Petroleum, petrochemical and natural gas industries – Sector-specific quality management systems – Requirements for product and service supply organizations
6. Quality Audits for Improved Performance, Third Edition, Arter, Dennis R.
7. Juran's Quality Handbook, Sixth edition
8. API 1173

Appendix B – GLOSSARY OF TERMS

American Society for Quality (ASQ) is a professional, nonprofit association which develops, promotes, and applies quality related information and technology for the private sector, the government, and academia. ASQ serves more than 108,000 individuals and 1,100 corporate members in the United States and 108 other countries.

Audit is the verification activity, such as inspection or examination, of a process or quality system, to ensure conformance to requirements. An audit can apply to an entire organization, or might be specific to a function, process, or production step.

Auditor is a qualified person who performs audits and/or reviews.

Checklist(s) are used to gather audit/review data. They frame the information the auditor needs to collect. During fieldwork, auditors use a checklist to record facts. All checklists used in an audit/review must be related to requirements.

Compliance is to meet prescribed acts, laws and regulations. (Note: A non-compliance is a particular case of a non-conformance.

Conformance is an affirmative indication or judgment that a product or process has met relevant internal and external requirements (e.g., company defined specifications, standards, and contracts; and state and federal regulations). (Note: Conformance includes compliance.)

Corrective Action is action taken to eliminate the cause(s) of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

Corrective Action Report (CAR) is a form used by the auditee to report and document actions to eliminate the cause of a problem reported as non-conformity, or a finding, during a quality audit.

International Organization for Standardization (ISO) is a network of national standard institutes from over 150 countries working in partnership with international organizations, governments, industries, businesses, and consumer representatives to develop and publish international standards; acts as a bridge between public and private sectors.

Measurement is the act or process of quantitatively comparing results with requirements.

Measurement System is all operations, procedures, devices, and other equipment or personnel used to assign a value to the measured characteristic.

Non-Conformance is a violation of requirements, or the nonfulfillment of a specified requirement.

Observation is a statement of fact made during an audit/review, and substantiated by objective evidence.

Plan-Do-Check-Act Cycle (P-D-C-A) is a four-step process for quality improvement. In the first step (plan), a way to effect improvement is developed. In the second step (do), the plan is carried out, preferably on a small scale. In the third step (check), a study takes place between what was predicted, and what was observed in the previous step. In the last step (act), action is taken on the casual system to effect the desired change. The Plan-Do-Check-Act Cycle is sometimes referred to as the Shewhart cycle because Walter A. Shewhart discussed the concept in his book, Statistical Method from the Viewpoint of Quality Control. The concept was popularized by W. Edwards Deming as the Plan-Do-Study-Act Cycle.

Preventive Action is action taken to eliminate the cause(s) of potential non-conformities in order to prevent future occurrence.

Procedure(s) is/are the steps in a process, and how the steps are to be performed for the process to fulfill a customer's requirements, usually documented.

Process is a set of interrelated work activities characterized by a set of specific inputs and value added tasks which consists of a procedure for a set of specific outputs.

Quality is conformance to requirements. It is the characteristics of a product or service which uphold its ability to satisfy stated or implied needs.

Quality Assurance (QA) comprises those actions necessary to provide adequate confidence that products, processes or systems comply with requirements such as regulations, internal procedures and standards. The focus is on providing assurance that processes are adequate and effective.

Quality Control (QC) comprises operational techniques and activities, including inspections, necessary to control the characteristics of a product or service (i.e. characteristics that can be measured against codes, drawings, specifications). The focus is on preventing defective products or services from being passed on.

Quality Management System is the organizational structure, procedures, processes, controls, and resources needed to achieve stated quality objectives.

Root Cause is an action or activity which results in a fundamental deficiency or nonconformance, and must be permanently eliminated to prevent recurrence of the same or similar nonconformance; source where the nonconformance originates.

Root Cause Analysis helps to identify causal factors, or the root cause. When the root cause is identified and corrected, the problem typically is fixed permanently. Without root cause analysis, solutions to the problem are often erroneous, and the problem could recur.

Sample is a finite number of items of a similar type taken from a population for the purpose of examination, and to determine if all members of the population conform to quality requirements or specifications.

Sampling is the process of selecting a suitable representative sample of a population or group in order to determine the characteristics of the whole population. Inferences about the entire group are based on facts discovered in a part of the group.

Specification(s) are a grouping of specific parameters required to ensure the success of a product to perform as designed, or a document which states the conforming requirements on a given product or service.