BEFORE THE PUBLIC UTILITIES COMMISSION
OF THE STATE OF CALIFORNIA

Order Instituting Rulemaking on the Commission's Own Motion to Adopt New Safety and Reliability Regulations for Natural Gas Transmission and Distribution Pipelines and Related Ratemaking Mechanisms.	Rulemaking 11-02-019 (Filed February 24, 2011)

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RESPONSE OF CALIFORNIANS FOR RENEWABLE ENERGY, INC. (CARE) TO MOTION OF PG&E

Pursuant to the April 25, 2011 Ruling of ALJ Bushey CAlifornians for Renewable Energy, Inc. (CARE) respectfully responds to Pacific Gas and Electric's (PG&E's) April 21, 2011 Motion asking the Commission make a finding regarding "whether its validation methodology is acceptable to the Commission".

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I. INTRODUCTION

On April 21, 2011, Pacific Gas and Electric Company (PG&E) filed and served its Motion for Adoption of a Maximum Allowable Operating Pressure Validation Methodology and also requested that the time for responding to the motion be shortened to five days. PG&E stated that a Commission response to the motion was purportedly urgently required as it is in the midst of the Commission-ordered validation effort and needs immediate guidance as to whether its validation methodology is acceptable to the Commission.[1]

Pursuant to Rule 11.1 of the Commission's Rules of Practice and Procedure, Pacific Gas and Electric Company ("PG&E") moves for an order adopting a methodology for the validation of the maximum allowable operating pressure ("MAOP") of PG&E's Class 3 and 4, and Class 1 and 2 high consequence area natural gas transmission pipelines ("HCA Pipelines"). This motion is made on the grounds that PG&E has embarked on the MAOP validation of PG&E's HCA Pipelines without pressure tests and needs guidance as to whether the methodology PG&E is using for the MAOP validation is acceptable to the Commission. Without such guidance, PG&E may complete a time-consuming and difficult MAOP validation process that does not satisfy the Commission's directive.

Because a Commission decision is needed urgently, PG&E requests that the time to respond to this motion be shortened to five days.

[1] CARE requests that the Commission direct PG&E to provide its future documents in searchable format.

II. PG&E'S MOTION IS PREMATURE AS THEY HAVE FAILED TO DEMONSTRATE THEY HAVE ANY QUALITY SYSTEM OR VALIDATION PROTOCOL

Essentially PG&E is asking the Commission to define the problem for which it is looking for PG&E to answer. PG&E's motion itself provides incontrovertible evidence that PG&E does not have any Quality System, Process validation, Installation qualification, Process performance qualification, Product performance qualification, Prospective validation, Retrospective validation, or a Validation protocol in place to allow the determination of "whether its validation methodology is acceptable to the Commission".

What isn't clear however is what exactly PG&E is offering for the Commission to approve and the Parties to review?

The Quality System (QS) defines process validation as establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.[2] The goal of a quality system is to consistently produce products that are fit for their intended use. Process validation is a key element in assuring that these principles and goals are met.

Processes are developed according to the design controls and validated and the process specifications, hereafter called parameters, are derived from the specifications for the device, component or other entity to be produced by the process. The

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[2] REFERENCES

1. Guideline on General Principles of Process Validation, May 1987, FDA, CDRH/CDER
2. Journal of Validation Technology, Vol. 1, No. 4, August 1995

parameters are documented in the device master record. The process is developed such that the required parameters are achieved. To ensure that the output of the process will consistently meet the required parameters during routine production, the process is validated.

The basic principles for validation may be stated as follows:

- Establish that the process equipment has the capability of operating within required parameters;

- Demonstrate that controlling, monitoring, and/or measuring equipment and instrumentation are capable of operating within the parameters prescribed for the process equipment;

- Perform replicate cycles (runs) representing the required operational range of the equipment to demonstrate that the processes have been operated within the prescribed parameters for the process and that the output or product consistently meets predetermined specifications for quality and function; and

- Monitor the validated process during routine operation. As needed, requalify and recertify the equipment.

A. TERMS AND DEFINITIONS

Terms other than those used herein may be found in the literature.

VALIDATION: confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled.

PROCESS VALIDATION: establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

INSTALLATION QUALIFICATION: establishing documented evidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.

PROCESS PERFORMANCE QUALIFICATION: establishing documented evidence that the process is effective and reproducible.

PRODUCT PERFORMANCE QUALIFICATION: establishing documented evidence through appropriate testing that the finished product produced by a specified process(es) meets all release requirements for functionality and safety.

PROSPECTIVE VALIDATION: validation conducted prior to the distribution of either a new product, or product made under a revised manufacturing process, where the revisions may affect the product's characteristics.

RETROSPECTIVE VALIDATION: validation of a process for a product already in distribution based upon accumulated production, testing and control data.

VALIDATION PROTOCOL: a written plan stating how validation will be conducted, including test parameters, product characteristics, production equipment, and decision points on what constitutes acceptable test results.

B. WHY VALIDATE PROCESSES

There are many reasons, in addition to the regulatory requirements, for validating processes. A manufacturer can assure through careful design of the device and packaging, careful design and validation of processes, and process controls, that there is a high probability that all manufactured units will meet specifications and have uniform quality. The dependence on intensive in-process and finished device testing can be reduced. However, in-process and finished product testing still play an important role in assuring that products meet specifications. Consistent conformance to specifications is likely to result in fewer complaints and recalls. Also, when needed, the validation files contain data to support improvements in the process or the development of the next generation of the process.

C. WHAT PROCESSES SHOULD BE VALIDATED

Where process results cannot be fully verified during routine production by inspection and test, the process must be validated according to established procedures. When any of the conditions listed below exist, process validation is the only practical means for assuring that processes will consistently produce devices that meet their predetermined specifications:

- Routine end-product tests have insufficient sensitivity to verify the desired safety and efficacy of the finished devices;

- Clinical or destructive testing would be required to show that the manufacturing process has produced the desired result or product.

- Routine end-product tests do not reveal all variations in safety and efficacy that may occur in the finished devices.[3]

- The process capability is unknown, or it is suspected that the process is barely capable of meeting the device specifications.

D. TYPES OF PROCESS VALIDATION

Process validation may be conducted at different points during the life cycle of a product. The types of process validation are defined in terms of when they occur in relation to product design, transfer to production and release of the product for distribution.

1. Prospective Validation

Prospective validation is conducted before a new product is released for distribution or, where the revisions may affect the product's characteristics, before a product made under a revised manufacturing process is released for distribution.

Concurrent validation is a subset of prospective validation and is conducted with the intention of ultimately distributing product manufactured during the validation study. Concurrent validation is feasible when nondestructive testing is adequate to verify that products meet predetermined specifications and quality attributes. If concurrent validation is being conducted as the initial validation of a new process or a process which has been modified, product should be withheld from distribution until all data and

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[3] For example, visual inspections usually are not capable of detecting defects in structural welds. Such defects may be detectable only by using destructive testing, expensive test equipment, or very slow test methods.

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results of the validation study have been reviewed, and it has been determined that the process has been adequately validated.

Concurrent validation may be conducted on a previously validated process to confirm that the process is validated. If there have been no changes to the process and no indications that the process is not operating in a state of control, product could be released for distribution before revalidation of the process is completed. There is some risk to early release of product in that subsequent analysis of data may show that the process is not validated.

2. Retrospective Validation

Retrospective validation is the validation of a process based on accumulated historical production, testing, control, and other information for a product already in production and distribution. This type of validation makes use of historical data and information which may be found in batch records, production log books, lot records, control charts, test and inspection results, customer complaints or lack of complaints, field failure reports, service reports, and audit reports. Historical data must contain enough information to provide an in-depth picture of how the process has been operating and whether the product has consistently met its specifications. Retrospective validation may not be feasible if all the appropriate data was not collected, or appropriate data was not collected in a manner which allows adequate analysis.

Incomplete information mitigates against conducting a successful retrospective validation. Some examples of incomplete information are:

- Customer complaints which have not been fully investigated to determine the cause of the problem, including the identification of complaints that are due to process failures;
- Complaints were investigated but corrective action was not taken;
- Scrap and rework decisions that are not recorded, investigated and/or explained;
- Excessive rework;
- Records that do not show the degree of process variability and/or whether process variability is within the range of variation that is normal for that process, for example, recording test results as "pass" or "fail" instead of recording actual readings or measurements results in the loss of important data on process variability; and
- Gaps in batch records for which there are no explanations. (Retrospective validation cannot be initiated until the gaps in records can be filled or explained.)

If historical data is determined to be adequate and representative, an analysis can be conducted to determine whether the process has been operating in a state of control and has consistently produced product which meets its predetermined specifications and quality attributes. The analysis must be documented.

After a validated process has been operating for some time, retrospective validation can be successfully used to confirm continued validation of that process if no significant changes have been made to the process, components, or raw materials.

Statistical process control is a valuable tool for generating the type of data needed for retrospective analysis to revalidate a process and show that it continues to operate in a state of control.

E. PROCESS VALIDATION STUDIES

1. Planning the Process Validation Study

Careful planning of a validation study is essential to ensure that the process is adequately validated. The plan should include design reviews. The plan for the validation study is documented in the validation protocol. A copy of the protocol and validation results are placed in the Design History File (DHF) or quality system record file. The operational, monitoring, and other production-related procedures are part of the device master record (DMR). Planning for the validation should include the following elements as well as any other relevant issues that must be addressed to conduct the validation study:

- identification of the process to be validated;
- identification of device(s) to be manufactured using this process;
- criteria for a successful study;
- length and duration of the study;
- assumptions (shifts, operators, equipment, components);
- identification of equipment to be used in the process;

- identification of utilities for the process equipment and quality of the utilities;
- identification of operators and required operator qualifications;
- complete description of the process {may reference the DMR};
- relevant specifications including those for the product, components, manufacturing materials, the environment, etc. [may reference the DMR and quality system files;
- any special controls or conditions to be placed on preceding processes during the validation;
- process parameters to be controlled and monitored, and methods for controlling and monitoring ;
- product characteristics to be monitored and method for monitoring;
- any subjective criteria used to evaluate the product;
- definition of what constitutes nonconformance for both measurable and subjective criteria;
- statistical methods for data collection and analysis;
- consideration of maintenance and repairs;
- conditions that may indicate that the process should be revalidated;

- stages of the study where design review is required; and

- approval(s) of the protocol.

The validation plan should also cover the installation and operation qualification of any equipment used in the process, process performance qualification, and product performance qualification.

2. <u>Installation and Operation Qualification</u>

After process equipment is designed or selected, it should be installed, reviewed, calibrated, challenged, and evaluated to ensure that it is capable of operating within established limits and tolerances as well as throughout all anticipated operating ranges. Installation and operation qualification studies establish confidence that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

The installation and operation qualification phases of process validation include:

- examining equipment design and supplied documentation;

- determining installation requirements;

- establishing any needed environmental controls and procedures;

- assuring that the work area has sufficient space to perform the processing and associated activities;

- installing the equipment;
- verifying correct installation;
- establishing manufacturing procedures for the monitoring, operation, and control of the equipment including the minimum number of operators;
- determining calibration, cleaning, maintenance, adjustment, and expected repair requirements;
- identifying important elements of the equipment that could affect the output or finished device;
- verifying that the system or subsystem performs as intended throughout all anticipated operating ranges; and
- documenting the above information.

Equipment fabricators may perform qualification runs at their facilities and analyze the results to determine that the process equipment is ready for delivery to the medical device manufacturer. Device manufacturers should obtain copies of the suppliers' qualifications studies to use as guides, to obtain basic data, and to supplement their own qualification studies. However, it is usually insufficient to rely solely upon the representations and studies of the equipment supplier. The device manufacturer is ultimately responsible for evaluating, challenging, and testing the equipment and deciding whether the equipment is suitable for use in the manufacture of a specific device(s). The evaluations may result in changes to the equipment or process.

Installation and operation qualifications should include establishing pertinent methods, procedures, and schedules for calibration, cleaning, and maintenance, and establishing a repair parts list for each piece of equipment. Planning for eventual maintenance and repairs can reduce or prevent confusion during emergency repairs which could lead to improper repairs such as the use of the wrong replacement part. Post-repair cleaning, calibration, and re-start requirements should be established if necessary to prevent inadvertent manufacture of nonconforming devices. The objective is to assure that all repairs can be performed in a way that will not affect the characteristics of material processed or devices manufactured after repairs.

Process and monitoring equipment (instruments) should be calibrated at the beginning of the validation study, and the calibration should be checked at the end of the study to establish confidence in the validation of the process. Equipment found out of calibration at the end of a process validation study may indicate that the process has not been operating in a state of control and cannot be considered validated. More frequent calibration or more robust equipment may be necessary, or you may wish to use stand-alone instruments in parallel with the built-in process monitoring equipment.

It is important to document installation and operation qualification studies. Such documentation can substitute for part of the requalification of equipment in future process validation studies. When equipment is moved to a new location, installation and operation should be requalified. By comparing data from the original installation and

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operation qualification and the requalification, the manufacturer can determine whether there have been any changes in equipment performance as a result of the move. Changes in equipment performance should be evaluated to determine whether it is necessary to revalidate the process.

3. <u>Process Performance Qualification</u>

The purpose of *process* performance qualification is to rigorously test the process to determine whether it is capable of consistently producing an output or in-process or finished devices which meet specifications. In entering the process performance qualification phase of validation, it is understood that the:

- device, packaging, and process specifications have been established, documented, and essentially proven acceptable through engineering, laboratory or other verification methods; and
- process and ancillary equipment and the environment have been judged acceptable on the basis of installation and operation qualification studies.

Challenges to the process should simulate conditions that will be encountered during actual production. Challenges should include the range of conditions allowed in written standard operating procedures and should be repeated enough times to assure that the results are meaningful and consistent. Challenges may need to include forcing the preceding process to operate at its allowed upper and lower limits.

Process and product data should be analyzed to determine what the normal range of variation is for the process output. Knowing what is the normal variation of the output is crucial in determining whether a process is operating in a state of control and is capable of consistently producing the specified output.

Process and product data should also be analyzed to identify any variation due to controllable causes. Depending on the nature of the process and its sensitivity, controllable causes of variation may include:

- temperature,
- humidity,
- variations in electrical supply,
- vibration,
- environmental contaminants,
- purity of process water,
- light, and
- inadequate employee training.

Appropriate measures should be taken to eliminate controllable causes of variation. For example, extreme variations in temperature can be eliminated by installing heating and air conditioning. Employee training can be improved and conducted more frequently, and employees can be monitored more closely to assure that they are properly performing the process. Eliminating controllable causes of variation will reduce variation in the process output and result in a higher degree of assurance that the output will consistently meet specifications.

After routine production begins, data derived from monitoring the process and output product can be analyzed for variation and compared to the normal range of variation. Such analyses can detect when the process output is shifting so that corrections can be made before, or soon after, nonconforming product is produced.

4. Product Performance Qualification

The purpose of *product* performance qualification is to demonstrate that the process has not adversely affected the finished product and that the product meets its predetermined specifications and quality attributes. Product performance qualification and design validation of initial finished devices are closely related. According to the design control requirements, design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Products used for design validation should be manufactured using the same production equipment, methods and procedures that will be used in routine production. Otherwise, the product used for design validation may not be representative of production units and cannot be used as evidence that the manufacturing process will produce a product that meets pre-determined specifications and quality attributes.

Design validation can be conducted using finished products made during process validation studies and will satisfy the need for product performance qualification. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing production units under actual or simulated use conditions. Original designs and design changes are subject to design control requirements. The results of design validation are subject to review under the design control review requirements.

F. DOCUMENTATION

The requirements for process validation and include documentation requirements for the process validation study phase as well as for routine production using a validated process. Records of validation activities and results must be maintained. Validation protocols and results may be filed in the DHF or in the QS files. Records must include the date and signature of the individual(s) approving the validation and, where appropriate, the major equipment validated. Procedures for monitoring and control of process parameters must be established and maintained for validated processes. Procedures for the operation, monitoring and control of processes are part of the DMR.

When a validated process is used for manufacturing finished devices, the process must be performed by a qualified individual. Records must be maintained of the monitoring and control methods and data; where appropriate, the individual(s) performing the process; the date performed; and major equipment used. The records should be maintained in the DHR.

G. REVALIDATION

As long as the process operates in a state of control and no changes have been made to the process or output product, the process does not have to be revalidated. Whether the process is operating in a state of control is determined by analyzing day-to-day process control data and any finished device testing data for conformance with specifications and for variability.

When changes or process deviations occur, the process must be reviewed and evaluated, and revalidation must be performed where appropriate. Review, evaluation, and revalidation activities must be documented.

Processes may be routinely validated on a periodic basis; however, periodic validation may not be adequate. More important is appropriate monitoring so that if problems develop or changes are made, the need for immediate revalidation is considered.

III. CONCLUSIONS

The Motion should be denied for all the reasons provided. Instead CARE respectfully requests PG&E be Ordered to provide the Commission evidence of its Quality System, Process validation, Installation qualification, Process performance qualification, Product performance qualification, Prospective validation, Retrospective validation, or a Validation protocol that is in place to allow the determination of "whether its validation methodology is acceptable to the Commission" based on the evidence therein presented.

Respectfully submitted,

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April 28, 2011

Verification

I am an officer of the Intervening Corporation herein, and am authorized to make this verification on its behalf. The statements in the foregoing document are true of my own knowledge, except matters, which are therein stated on information and belief, and as to those matters I believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 28th day of April 2011 at Soquel, California.

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Certificate of Service

I hereby certify that I served the foregoing document "*RESPONSE OF CALIFORNIANS FOR RENEWABLE ENERGY, INC. (CARE) TO MOTION OF PG&E*" under CPUC Docket R.11-02-019. Each person designated on the official service list, has been provided a copy via e-mail, to all persons on the attached service lists on April 28, 2011 transmitting the copies via e-mail to all parties who have provided an e-mail address. First class mail will be used if electronic service cannot be effectuated.

I declare under penalty of perjury that the foregoing is true and correct.

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