Generic Qualification and Dedication of Digital Components

Project Status and Lessons Learned

Technical Report

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REPORT SUMMARY

As its nuclear power plants age, the electric power industry is focusing on the development of cost-effective replacements for many obsolete components used in instrumentation and control systems. This report documents lessons learned from a number of pilot applications of an approach developed by EPRI for evaluating commercial digital equipment to assess its adequacy for nuclear safety applications. The subjects of the exercise were commercially available single loop controllers, valve positioners, a smart pressure transmitter, and a circuit breaker over-current trip device. All have broad applicability as replacements for obsolete components currently used in nuclear plants.

Background

Utilities are utilizing commercial digital equipment more and more, but their processes and procedures for evaluating such equipment to ensure adequate quality for nuclear safety-related applications are still developing. Significant licensing uncertainty remains, and utilities have been hesitant to commit resources to such efforts. EPRI has developed an approach for these evaluations and has obtained Nuclear Regulatory Commission (NRC) concurrence that the approach is acceptable. However, experience with the approach is limited; and questions remain as to how it can be applied in a way that is both technically defensible and cost-effective. Utilities needed pilot applications of the approach on real components to demonstrate details of its use and ensure the ultimate acceptability of future qualifications for similar devices.

Objectives

To make selected commercial digital components available for nuclear safety systems by performing tests and evaluations qualifying them for such applications; to help clarify and stabilize the regulatory environment for commercial digital components in nuclear plants; to demonstrate the approach for evaluating commercial digital equipment described in EPRI report TR-106439, *Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications,* and EPRI report TR-107339, *Evaluating Commercial Digital Equipment for High Integrity Applications*.

Approach

The project team began by identifying high-priority components—devices that are likely replacements for equipment that is obsolete, but still widely used in safety systems. The initial list included single loop controllers, smart transmitters, time delay relays, recorders, circuit breakers and pressure switches. Participating utilities then selected specific models well suited to their planned applications for more in-depth assessment and, ultimately, qualification. Qualification activities included various tests and evaluations that give indications of the quality and adequacy of design of the component and its software and demonstrate that it can meet the requirements of nuclear safety-related applications. The qualification/dedication activities were

performed under nuclear quality assurance (QA) programs. All evaluations were performed generically to the extent feasible, with the intent of qualifying the device for a broad a range of applications. For the first two components evaluated, the project team performed all the evaluation and testing activities and documented them in EPRI reports. To use one of these devices, a utility would purchase the device from the commercial supplier and then perform a commercial grade dedication, using the EPRI reports for much of the documentation. For the rest of the devices, the equipment suppliers led the qualification activities, either under their own nuclear QA program or working with an affiliate organization under its QA program. The entity with the nuclear QA program could then sell these devices as qualified 1E components with no additional commercial-grade dedication step needed.

Results

This report summarizes the activities and lessons learned from the qualification efforts, including the screening activities conducted by the EPRI working group that guided the project. Generally speaking, the components investigated in this study were designed and manufactured using commercial practices, rather than the more stringent QA processes required when components are built specifically for nuclear safety systems. Had they been developed under a nuclear-grade QA program, the documentation might have been more complete, the design more rugged, and the testing activities more extensive. Still, good commercial practices and evolutionary design processes have resulted in relatively simple, reliable devices with successful operating histories. Since the qualification/dedication process for digital components can be quite open-ended, with correspondingly high costs, it is important to keep the effort as focused as possible. The report contains lessons learned that will help streamline future qualification efforts.

EPRI Perspective

This exercise is an excellent example of how EPRI guidelines on commercial-grade digital equipment can be used to extend the traditional equipment qualification/dedication process to software-based systems. While the lessons learned are based on the experience of a utility working group and the EPRI project team, most of them apply directly to any situation where a utility or group of utilities are working to find and qualify/dedicate digital components to replace obsolete components in safety-related or critical-to-plant operation applications. The report will be helpful in supporting and guiding future qualification and commercial-grade dedication efforts.

Keywords

Digital upgrade
Instrumentation and control
Qualification
Commercial-grade item dedication
Commercial off-the-shelf software
COTS

ABSTRACT

The EPRI Component Qualification User Group consists of a group of engineers representing nuclear utilities that share a common interest in the generic evaluation and qualification of commercial digital instrumentation and control (I&C) components for nuclear safety related applications. The User Group previously sponsored generic qualification of two types of commercial digital components: single loop controllers and a smart transmitter. These projects were pilot applications of the approach documented in EPRI TR-106439 and further detailed in EPRI TR-107339. Lessons learned from these initial pilots are documented in EPRI Report 1001452 dated September, 2001.

For both the single loop controller and smart transmitter efforts, there was clear direction as to the specific type of component and even the specific vendor and product model to be considered by the group for evaluation. In 2002, however, there was no such clear agreement within the group, with as many as 13 different types of components identified as desired candidates for evaluation or qualification from the seven utility members. As a result, the User Group sponsored the development of a screening process to (1) determine which component types identified have the highest common interest within the group, (2) define the intended applications and requirements for these components, (3) identify the specific device models that meet these requirements, (4) evaluate specific device and vendor capabilities as applicable to a nuclear qualification effort, (5) develop a generic evaluation, qualification, and dedication strategy for each candidate device based on this evaluation, and ultimately (6) select the best candidate vendors and devices to participate in the project qualification activities based on the available project resources. The project subsequently supported the qualification efforts for several commercial digital devices, including current-to-pneumatic valve positioners and a circuit breaker over-current trip device, following the strategies developed during the screening process.

This report describes the lessons learned from the development and execution of the aforementioned screening process and the additional lessons learned during the subsequent evaluation and qualification efforts. In doing so it revisits the lessons learned from the initial pilot programs, documented in EPRI Report 1001452, to provide a complete collection of the lessons learned to date.

This project is part of a larger effort to address the obsolescence of analog components and the lack of a mature process for evaluation and qualification of commercial digital components for safety related applications. Overall, the effort confirmed both the difficulty of bringing commercial suppliers into the nuclear safety market and the benefits of approaching vendors as an industry through organizations like the EPRI Component Qualification User Group, rather than on a utility-by-utility basis. It also confirmed the advantages of working with suppliers that either have a 10 CFR 50 Appendix B quality assurance program or can distribute their equipment to the nuclear industry through an affiliate that has an Appendix B program.

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INTRODUCTION

As nuclear plants replace obsolete instrumentation and control (I&C) equipment, they will increasingly turn to commercial grade digital components, even for safety related applications. This requires that various evaluations and qualification tests be performed before the components can be used in the plants, and the cost of these qualification activities can easily dwarf the cost of the components. Additionally, the digital replacements, while superior to the analog equipment in many respects, tend to become obsolete far more quickly. The owner-operators of nuclear plants therefore need a methodology for qualifying such equipment that is streamlined and cost effective, as well as technically defensible, and they need to become proficient at using it.

For most of the self-contained components addressed in this activity, the vendors are hesitant to engage the nuclear industry, which represents a very small fraction of their market and can involve significant extra commitments to meet the quality assurance (QA) and documentation requirements. This activity allows the nuclear utilities to engage the equipment suppliers as a group, working with them to address the nuclear specific requirements on a one-time basis, and thereby making it practical for them to participate. The equipment suppliers broaden their markets, and the nuclear utilities get access to high quality commercial digital components that can help them improve plant performance, reliability and safety.

The project previously sponsored generic qualification activities for two single loop controllers and a smart transmitter, following this group approach. Lessons learned from these pilot qualifications are documented in EPRI Report 1001452, *Generic Qualification of Commercial Grade Digital Devices: Lessons Learned from Initial Pilots* [1]. The report was organized to cover lessons from the various aspects of a generic qualification effort, including:

- Section 2, *Selecting Devices and Vendors*
- Section 3, *Project Planning*
- Section 4, *Commercial Grade Survey and Critical Design Review*
- Section 5, *EMC Qualification*
- Section 6, *Other Qualification Test Lessons*

This report addresses the additional lessons learned from the subsequent generic qualification activities since the initial pilot efforts. These activities include the development of a screening methodology to select candidate components for group-sponsored generic qualification, and the qualification of the specific devices selected through application of the screening process.

At the time of this report, the project team is actively engaged in qualification activities with digital valve positioner vendors, a circuit breaker trip device vendor, and a vendor of a handheld device used as a support tool for testing, calibration and configuration of many digital devices, including several that the generic qualification effort has examined.

Background

Operating nuclear plants for the most part still use analog I&C equipment that was designed and built decades ago under specialized nuclear quality assurance programs. In the intervening years, most industries have transitioned from the analog technology used in the nuclear plants to digital technology, and the vendors have updated their product lines accordingly. When nuclear plant design and construction stagnated in the 1970s, the demand for nuclear qualified equipment declined to the point where few vendors maintained their nuclear quality assurance (Appendix B) programs or their qualified products. Processes were developed to qualify and dedicate many types of commercial components for use in nuclear safety applications, but this did not extend to software-based I&C equipment. The result is that most operating nuclear plants are using a great deal of obsolete analog I&C equipment for which qualified replacements simply do not exist.

The impact of equipment obsolescence is amplified by the fact that most nuclear plants are now planning to extend their operating licenses by twenty years. Just a few years ago, most plants were planning to nurse the old equipment along until the plant license expired, and then shut down. Now, with renewed emphasis on extending the usefulness of existing power generation assets, most nuclear plants are looking ahead to decades of operation, and continued maintenance of the obsolete equipment is no longer a practical or cost effective option. Declining reliability is just the tip of the iceberg. Repair often is difficult or impossible without reverse engineering or manufacturing custom parts, and the needed expertise on both the analog technology and the power plant systems is gradually being lost as the workforce ages and retires. To meet reliability and availability goals, the plants have no option but to replace their obsolete control equipment over the next several years. With the lack of available nuclear qualified I&C equipment, an increasing number of nuclear plants are looking to commercial digital I&C products to address these obsolescence issues.

Qualification and dedication of commercial equipment for safety related applications is more complex for digital than for analog equipment. It requires assessments of such things as software quality, software architecture, fault tolerance, and other issues that need special attention for digital technology. EPRI developed an approach for evaluating commercial digital equipment, documented in EPRI TR-106439, *Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications* [2] and EPRI TR-107339, *Evaluating Commercial Digital Equipment for High Integrity Applications* [3]. EPRI TR-106439 has been reviewed and endorsed by the U.S. Nuclear Regulatory Commission, but the approach is still quite new to both licensees and regulators, and the details on how to best apply it are still evolving. At this point, qualification of a digital device can be far more complex and expensive than for other types of equipment, and there is no guarantee that the device can be qualified successfully. For many relatively inexpensive components and devices, neither the manufacturer nor individual utilities can practically bear the risks associated with such an effort. The process needs to be improved to the point where utilities and suppliers can engage in a qualification and dedication effort with predictable costs and schedule, and with high confidence in its ultimate success in regard to both technical and regulatory challenges. Given the risks and uncertainties, individual utilities are typically hesitant to engage commercial vendors in projects to attempt to qualify and dedicate digital I&C components.

Component Qualification User Group

The Component Qualification User Group was formed in part to allow nuclear plants to approach the commercial digital equipment suppliers as an industry rather than on a plant-by-plant basis. This group approach was developed to conserve resources for both individual utilities and the commercial equipment vendors, and also to reduce the regulatory risks associated with using commercial digital components. The components of interest to the User Group (and to other nuclear utilities) are typically self-contained devices that are relatively inexpensive, ranging in cost from a few hundred to several thousand dollars, and that are used in many applications in the plants. For these devices, the qualification costs far exceed the component costs.

Previous Pilot Qualification Projects

The Component Qualification User Group has previously sponsored generic qualification activities for two types of commercial digital components: single loop controllers and a smart transmitter.

Single Loop Controllers

The project supported qualification activities for two commercially available single loop controllers, the Honeywell UDC3300 and the Bailey-Fischer & Porter 53SL6000. These devices were selected based almost solely based on previous utility experience with the devices in non-safety applications and the associated comfort level with the specific devices. The project team, with support from the sponsoring utilities, conducted all qualification activities, including technical support for the commercial grade survey, developing specifications for and witnessing seismic, environmental and electromagnetic compatibility (EMC) testing, and performing the Critical Digital Review (CDR, see EPRI TR-107339 for additional details on the CDR) and the baseline functional and challenge testing. The controller vendors provided access to cognizant engineering staff and documentation on their development and quality processes, but did not perform or document the qualification testing, commercial grade survey, or the CDR.

The end result of these qualification efforts was a report documenting the results of the evaluations and qualification activities, but not a “dedicated” or “fully qualified” device. Although most of the qualification and dedication activities were complete, for utilities to use the controllers in safety related applications, they still would be required to procure the device from the component vendor, obtain the qualification report from EPRI, and perform their own commercial grade dedication of the device for their specific intended application. Additionally, EPRI remained responsible for 10 CFR Part 21 notification and for evaluating ongoing vendor hardware and software design changes to the commercial model to determine whether they could be incorporated into the “frozen” nuclear model. From the utility perspective, this reduces the risks associated with the qualification and dedication effort, but did not eliminate the effort. The implementation process is still very cumbersome compared to purchasing a pre-qualified device from a supplier under a nuclear (Appendix B) quality assurance program.

Smart Transmitter

The smart transmitter effort followed a different approach. In this case, Rosemount Nuclear Instruments, Inc. (RNII), a vendor with an Appendix B program, qualified and dedicated the 3051C smart transmitter manufactured commercially by a sister division of Rosemount, Inc. (now Emerson Process Management). RNII conducted the majority of qualification activities and currently maintains the qualification and sells the transmitters as qualified 1E components directly to the utilities. The project supported the qualification effort by providing specific evaluations to augment RNII's capabilities, including the CDR, an independent review of the commercial EMC testing against nuclear industry requirements, and a "Preponderance of Evidence" evaluation summarizing the transmitter dedication critical characteristics and how they were verified by RNII. RNII will maintain the qualification throughout the product life, including Part 21 notification and evaluation of design modifications to the nuclear model.

The smart transmitter CDR also included an evaluation of the HART® 275 Handheld Communicator for use as a support tool to test, configure and calibrate the 3051C transmitter. The 275 Communicator is developed and maintained by Rosemount.

This project model is clearly preferable over that used for the single loop controllers. It enables nuclear plants to procure a qualified 1E component directly from the vendor without having to perform commercial grade dedication activities. It also uses the best qualified entity to perform the long term maintenance of the qualification, which helps ensure that product changes are addressed appropriately.

Qualification Projects beyond the Pilots

For the single loop controller and smart transmitter efforts, there was clear direction as to the specific type of component, and even the specific vendor and product model, to be considered by the group for evaluation. In 2002, however, there was no such clear agreement within the group, with 13 different types of components identified by user group members as desired candidates for evaluation and qualification:

I/P transducer/positioner	Recorder	Inverter
Temperature controller	Solid state relay	Pressure switch
Breaker controller	Time delay relay	Indicator
Radiation monitor	MCC starter	
Power supply	Smart vibration probe	

Not immediately focusing on specific brands and models was an advantage to the extent that it did not lock the effort into specific devices; it allowed more of a "best of class" approach. However, it also required developing a methodology to identify the most promising components, vendors and specific devices to ensure high probability of success at the most reasonable cost. Accordingly, a screening methodology was developed for narrowing this broad list down to a limited, manageable number of specific device models with a strong chance of successfully completing qualification testing and evaluation activities. The preliminary concept of the methodology included the following activities:

- Based on User Group input, establish basic requirements for the components of highest interest, including intended applications for the device, safety significance of the applications, functional requirements, accuracy, dynamic response, inputs and outputs, diagnostic capabilities, acceptable failure modes, etc.
- Develop a preliminary list of candidate devices for each component types. Perform preliminary screening by reviewing available product literature to identify the most promising candidates of each component type for further vendor screening.
- Perform vendor screening of the most promising candidate devices for each component type. Contact candidate vendors to determine their willingness to participate in a generic qualification program, freeze device hardware and software versions (if necessary) for nuclear applications, and allow access to their facility and personnel for the performance of a CDR. Assess the likelihood of successfully completing a CDR based on the vendor's response to questions about the device hardware and software architecture, vendor software development practices, and other questions related to the design integrity, built-in quality, and dependability of the device.
- Develop a qualification strategy for each candidate device, including an estimate of the scope of the qualification activities necessary to generically qualify the device. The preliminary qualification strategy concept included using project resources for performance of the CDR and informal EMC testing at the Tennessee Valley Authority EMC laboratory. User Group members also sponsored seismic testing at the SQURTS facility, to augment vendor capabilities and help the vendors offset qualification costs. Additionally, the strategy included the option of finding a third-party dedicator to participate in, cosponsor and ultimately maintain qualification of the device to supply it 1E directly to the nuclear utilities in case the device manufacturer did not have the required capabilities or was not willing to perform the dedication and supply the device.
- Select the specific devices and vendors for further consideration and participation in the project.

The goal in performing the screening process, selecting the specific devices, and ultimately performing qualification activities was to apply the lessons learned from the initial pilot qualifications [1], most importantly to attempt to follow the smart transmitter project model, where an Appendix B vendor or third-party dedicator would ultimately supply the pre-qualified device 1E directly to the nuclear utilities.

As described in the following sections of this report, the actual screening methodology evolved as additional information was learned about the most preferable components and the number of candidate devices and capable vendors available for the components under consideration. Based on the results of the screening process and input from the User Group, qualification activities were pursued for the following components:

- **Digital Valve Positioner**: Three vendors, all with Appendix B affiliates within their corporate organization, were invited to participate in the project.
- **Circuit Breaker Over-Current Trip Device**: One vendor and third-party dedicator team was invited to participate.

- **Temperature Controller**: The project strategy was to locate a third-party dedicator to take ownership and ultimately maintain the nuclear qualification of one of the previously qualified single loop controllers. However, this requires active participation of the controller manufacturers, who in this case, were unable to justify commitment of resources to such an effort.
- **375 Field Communicator**: In May 2003, Emerson Process Management announced that the HART® 275 Handheld Communicator would be replaced with the new Model 375 Field Communicator. Many of the components evaluated by the Component Qualification Group, including the 3051C smart transmitter and the three digital valve positioners, relied on the 275 as a support tool for diagnostics, configuration, and maintenance. The project evaluated the Model 375 Field Communicator to ensure that the evaluated parts (and other HART®-based digital devices) remain viable replacements for obsolete equipment.

Contents of this Report

At the time of this report, a variety of evaluation and qualification activities have been completed for each of the three digital valve positioners, a circuit breaker over-current trip device, and the 375 Field Communicator. Efforts to expand the single loop controller qualification to include temperature control functions were ultimately unsuccessful based on lack of interest from the controller vendor. After performing some qualification activities, one of the digital valve positioner vendors abandoned the project, presumably due to the potential cost of completing the effort.

The goal of this report is to describe the lessons learned from developing and implementing the screening methodology and from the various qualification activities performed for the above components. The lessons fall into several categories, and for compatibility with EPRI Report 1001452 [1], the report is organized accordingly:

- Section 2, *Component Screening Process*, covers lessons learned from the development and implementation of the screening process, up to the point of developing a qualification strategy for the specific components (comparable to Sections 2 and 3 of [1]).
- Section 3, *Qualification Strategy*, describes lessons learned from the development of qualification strategies when working with vendors or third-party dedicators with 10 CFR 50 Appendix B QA programs (comparable to Section 3 of [1]).
- Section 4, *Critical Digital Reviews* (comparable to Section 4 of [1]).
- Section 5, *EMC Qualification* (comparable to Section 5 of [1]).
- Section 6, *Other Qualification Test Lessons*, covers lessons learned from radiation and seismic testing (comparable to Section 6 of [1]).
- Section 7, *Conclusions*, revisits the lessons from EPRI Report 1001452 to assess whether they were reinforced or modified by the subsequent qualification activities, and presents the overall conclusions from the generic qualification effort to date.
- Section 8, *References*, gives citations for documents that are referenced in this report.

The lessons documented in this report were learned through generic qualification projects involving the Component Qualification User Group and component suppliers. However, most are also applicable to an individual utility working with a preferred supplier to qualify and dedicate needed equipment.

2
COMPONENT SCREENING PROCESS

As discussed previously, for the pilot qualification efforts there was clear direction as to the specific components, vendors, and product models to be considered in the generic qualification effort. As such, formal "screening," as defined in this section of the report, was not performed in advance of initiating the qualification efforts. EPRI Report 1001452 [1] does, however, present some lessons learned related to a screening process from a retrospective evaluation of the pilot projects. These lessons relate to:

- The degree to which the results of commercial qualification testing or certifications already performed can be used to demonstrate compliance with nuclear qualification requirements.
- What measures should be taken, if any, to "harden" or extend the capabilities of the device beyond the commercial specifications to meet nuclear qualification requirements (e.g., to add an external EMC filter or surge suppressor).
- The complexity of the device including its internal architecture, external interfaces, and built-in software.
- The operating history of the device – how much documented operating history exists, how relevant it is to the generic qualification, and how well the device has performed.
- The level of involvement and cooperation of the vendor in the qualification effort.
- The definition of end user input in establishing the basic functional requirements and the desired features, functions and configurations for the device.
- The maintenance of the device qualification over the long term, including fault and failure tracking and reporting, configuration management, and design modifications.

Based on the 13 candidate components identified by the User Group in 2002, it was necessary to implement a more formal screening methodology. This screening process, including the results as applied to the 13 candidate component types, is fully described in EPRI Technical Update 1006842, *Generic Qualification/Dedication of Digital Components: Screening of Candidate Components* [4]. The first step in the overall screening process was to narrow the list of candidate components down to a more manageable number. The project ultimately concluded that four components was a small enough number to be manageable for a screening effort based on available resources, but large enough to ensure the top choices of most group members were represented. Applying a lesson learned from the initial pilot qualification projects, it then was necessary to define the requirements and intended applications for these top four components early in the screening process, prior to identification of candidate devices and vendors.

Once these requirements and applications were defined, device and vendor screening was conducted to locate capable devices, interact with the device vendors to learn about their devices and their development processes, educate commercial vendors about the unique aspects of digital device qualification and dedication for the nuclear industry, and ultimately determine which candidate vendors had the best chances of successfully completing a generic qualification effort.

The process and results are first summarized here to provide the necessary background information to understand the lessons learned that follow.

Selection of Candidate Components

The methodology applied to reduce the list of 13 candidate components down to a final four for further evaluation was based on a simple vote among the User Group members, and thus is not described in great detail here. Of greater interest are the results of this voting process, both in the components of most interest to the group and in the dynamics of interacting with the group to finalize the component choices.

Results of the Component Selection Process

The results of the voting process identified the following top choices:

- #1 Power supply
- #2 I/P (current to pneumatic) transducer, or air-operated valve positioner
- #3 Radiation monitor
- #4 Temperature controller or switch

The results showed a strong consensus in regard to the components of greatest interest. Each of the six group members that voted had their top component in the final list of four. The Group subsequently discussed the validity of two of these top four candidates. For power supplies, it seemed possible that the desired reliability and functionality could be achieved with existing qualified analog 1E devices. For radiation monitors, some existing 1E qualified digital components were initially identified, and another nuclear industry owners' group (BWROG) was actively evaluating the needs of their members, including the possibility of digital upgrades. The votes were recalculated after eliminating these two components, which added pressure switches, breaker controllers, and inverters for consideration.

The end result of the component selection process was that I/P transducers (air-operated valve positioners) and temperature controllers or switches were classified as definite finalists, power supplies and radiation monitors were considered possible finalists, and breaker controllers were considered an alternate. Although the User Group did not identify any potential third-party dedicators, this was still considered the likely method to execute and ultimately maintain the generic qualification program.

Definition of Component Requirements

Defining the requirements for generic qualification of a specific component is a critical step in the overall screening process. This information is vital both as a prerequisite to searching for capable devices and as a means of communicating the needs and the potential market for the component to the device vendors during the subsequent vendor screening process.

2002 Requirements Definition – I/P Transducers, Temperature Controllers, Power Supplies, and Radiation Monitors

A questionnaire-style survey was used to capture requirements for the candidate components that would cover a broad range of potential applications. A generic survey applicable to any digital component is included in Appendix A of this report. The survey was organized into different sections to define various aspects of the utility requirements, described as follows:

- **Application Requirements**: Intended applications for the component, number of intended safety related applications, description of interfacing systems, description of the existing component being replaced (analog or digital), safety and economic significance of the intended application. As learned in the initial pilot programs, the cost and scope of a qualification effort is significantly influenced by the desired application. For example, the required level of software verification and validation from a commercial vendor would be significantly higher for a device planned to be used in a reactor protection application as opposed to a control room HVAC application.
- **Physical Requirements**: Installation and mounting, power supplies, number and type of inputs and outputs, communication capabilities, mechanical requirements such as materials or pressure rating, etc. (see Section 4.2 of EPRI TR-106439).
- **Performance Requirements**: Environmental (seismic, EMC, radiation, temperature, humidity, etc.), accuracy, time response, drift, dead band, behavior under faulted conditions, diagnostics, HMI functionality. The survey attempted to separate the mandatory, basic functional requirements from the optional features that can inadvertently and unnecessarily increase the cost and scope of a qualification effort.

The survey also included sections for User Group members to provide additional potentially important information regarding specific vendors or devices based on any previous operating history in non-safety applications, and for documenting any other information relevant to the component and application under consideration.

Results of the 2002 Requirements Definition Process

Requirements surveys were forwarded to the User Group members with the highest interest in each component to gather their input. However, phone interviews typically proved more effective than asking the Group members to fill in the survey themselves. In some cases, a second call was necessary involving additional utility personnel (e.g., system engineers or maintenance managers) to complete certain survey questions. Consolidated survey responses for radiation monitors, I/P transducers, and temperature controllers were developed based on the input from the User Group.

Ultimately, the User Group reached agreement to formally drop power supplies and radiation monitors from further consideration. In both cases it was determined that existing, available 1E devices could meet the current needs.

2003 Requirements Definition – Breaker Control Devices

The “breaker controller” component selected by the User Group in 2003 was not specifically defined. This could refer to an over-current trip device, protective relays, or some other control equipment associated with nuclear plant circuit breakers. A key first step in the screening process was to specifically define the real needs for a breaker control device, with industry input beyond the Component Qualification User Group. A survey (Appendix B of this report) was distributed to both the project User Group and to the larger NMAC User Group to better define the anticipated utility needs to ensure that the most appropriate devices were selected. The survey results provided the needed application requirements and narrowed the focus of the generic qualification effort to over-current trip devices.

Results of the 2003 Requirements Definition Process

- The shortened version of the requirements survey was successful in defining “Application Requirements” for over-current trip devices.
- An investigation of the breaker control device market discovered four vendors that manufacture digital over-current trip devices for the User Groups’ desired applications.
- Digital over-current trip devices would likely be procured with replacement breakers rather than as stand alone devices.

At this point, further definition of physical and performance requirements was not necessary based on the limited number of potential devices and the fact that the trip devices are generally integrally paired to a replacement circuit breaker. In the next phase of the screening process, the device vendors were contacted to determine whether they were interested in a joint qualification effort.

Device and Vendor Screening

The device and vendor screening process is performed to help ensure a high probability of project success without performing detailed equipment and vendor evaluations. Screening activities include the following steps, which are described in detail in [4] and are summarized below:

- Identify capable devices,
- Connect with the commercial device vendors to learn about their devices and development processes,
- Educate the vendors about the unique aspects of digital device qualification for the nuclear industry, and
- Determine which candidate vendors have the best chances of successfully completing a generic qualification program.

Device screening includes searching for available devices and assessing their ability to perform User Group requirements based on available documentation. The first step in this process is to locate candidate devices via the internet, journal articles and recommendations directly from the User Group. As many digital components use some external communication protocol, the HART® Foundation website, www.hartcomm.org, and the Foundation Fieldbus website, www.fieldbus.org, are valuable sources of information for available products (the HART® site identifies 27 different component types and includes over 120 different vendors). Note that this approach keeps the options open for a "best of class" selection process, rather than committing to a specific device or supplier without consideration of their likelihood of success in the various evaluations and qualification tests that will be needed. The 'best' candidate might not be the component with the best functionality, because the qualification and dedication costs far exceed the component costs. The most appropriate candidate might be the one that is the best prepared for the generic qualification activities and the most committed to its success.

Most vendors have device specifications and even product manuals available on their product websites. This information provides a first look at device capabilities and can be used to quickly identify which vendors should be contacted. The main goal in reviewing vendor literature is to learn enough about the device to be effectively conversant with vendor technical representatives during the next step of the screening process.

Vendor screening involves three interrelated activities:

- continuing to screen the device for its capabilities to meet User Group requirements and for the likelihood of successfully completing a generic qualification program,
- educating the vendors about the User Group, the needs of the nuclear industry, and what is involved in a digital device generic qualification project, and
- identifying the vendors that are seriously interested in the project.

This phase of the screening process typically started with conversations with product managers or marketing managers about the above topics. Those who expressed initial interest received a follow-up letter that described the generic qualification process. The letter also contained two enclosures that the vendors were requested to complete to facilitate the screening process. The first enclosure formally documented the consolidated requirements defined by the User Group, and the vendors were asked to document how their device specifications compared to these requirements. The other enclosure contained a list of questions to help assess the cost and likelihood of successfully completing a qualification effort. The questions focused on

- the complexity of the internal hardware and software architecture of the device,
- the vendor's software development, testing, configuration management and change control practices and how they compare to those required from a nuclear quality assurance program,
- the extent and relevance of operating history information available for the device,
- the extent and scope of previously performed qualification testing to document conformance to published specifications, and
- the level of interest and extent of the vendor's participation in a generic qualification program.

These questions were derived from the dependability characteristics discussion in Section 4.2 of EPRI TR-106439 [2] and from the lessons learned from the initial pilot qualification programs [1]. Appendix C of this report documents the User Group consolidated requirements for digital valve positioners and the screening questions applicable to any commercial digital device that were forwarded to the vendors.

Committing to a qualification and dedication effort requires significant vendor resources for a relatively small potential market, and vendors often struggle internally with cost justification issues. During the time the vendors were preparing responses to the requirements and survey questionnaire, the vendors were provided with additional information to help them understand the nuclear market and unique aspects of generic qualification of a commercial digital device. Vendors were directed to the EPRI website that described the Rosemount smart transmitter generic qualification project. Additionally, conference calls were held with interested vendors to share information with multiple personnel in the vendor's organization.

Device and Vendor Screening Results for Digital Valve Positioners

User Group members were asked to identify any desirable candidate devices to initiate the device screening process. Digital valve positioners were different from the previous pilot qualification projects in that there were no clear preferences or favorite devices identified by the group. Again, this left the door open for a "best of class" approach. Several of the more well known I/P vendors were mentioned, and most group members indicated a preference to work with a reputable, established vendor expected to support their product line well into the future. The HART® website proved to be a useful source for locating possible devices, identifying 34 valve positioners from 20 different vendors, and in some cases providing direct links to the product website. No device or vendor was identified through any other source that was not on the HART® website list.

The screening process was continued for the 20 vendors identified on the HART® website. Initial steps included web searches for device literature and discussions with vendor technical representatives about their product lines and the capabilities of the device most appropriate for the needs of the nuclear utilities. Of the 20 initial vendors, six were promptly eliminated from consideration based on obvious noncompliance with User Group requirements or lack of vendor interest.

The remaining 14 vendors can be grouped into two separate categories: commercial vendors that have an affiliated company with a 10 CFR 50 Appendix B quality assurance program within their corporate organization (e.g., the smart transmitter example described in Section 1); and commercial vendors with no Appendix B affiliates. The results of the screening process as applied to each category of vendor are described separately below.

Vendors with 10 CFR 50 Appendix B Affiliates

Seven of the 14 vendors had an affiliated Appendix B company within their organization. In all cases, this affiliate manufactured and sold N-stamped control valves to the nuclear industry. None of the affiliates had any direct experience in qualifying or dedicating software-based digital devices; several had used software-based systems as measurement and test equipment to support qualification testing for their control valves.

All seven vendors expressed a strong interest in participating in sponsored generic qualification activities, seeing the opportunity to sell a qualified positioner as a natural match for their N-stamped control valve sales. Each vendor was provided with a copy of EPRI TR-106439 and the requirements and screening questionnaire, and was informed about the project via conference calls and the EPRI website.

One vendor ultimately withdrew its device from consideration; although greatly interested, they could not commit the necessary resources to the project. Two other vendors were eliminated because their devices were manufactured within the same corporation as other devices among the remaining candidates; the corporations selected the product line that best met the needs of the nuclear industry.

The remaining four vendors were requested to submit responses to the requirements and screening questionnaire. Most missed several promised deadlines. This may indicate that the nuclear market is a lower priority because it is seen as relatively small and difficult to service. Generally, all vendors had no difficulty completing the device requirements portions of the questionnaire. The screening questions (shown in Appendix C) proved more difficult for the vendors to generate the expected level of detail in their responses, as summarized below:

- **Device Architecture Questions**: All four vendors provided complete responses to these questions, including type of microprocessor, approximate size of code, and a description of the operating system and internal device communications.
- **Questions to Assess Dependability**: The responses to these questions were generally less detailed than anticipated. Most vendors described when the software was originally developed and the present amount of legacy code. However, little useful information was obtained about software verification and validation (V&V) or other software development practices. A typical response to this question was that V&V was performed per "internal company procedures."
- **Operating History Questions**: Three of the four vendors answered these questions, with only two fully describing the software release history and the corresponding number of units of each release in the field.
- **Qualification Testing Questions**: Three of the four vendors answered these questions. The responses gave a good general overview of what type of testing had been performed that could be applied to a nuclear qualification program. One vendor provided a test report from an independent test laboratory that verified device accuracy, performance, and environmental specifications, as well as response to certain abnormal events such as power interruption. All four devices had the CE mark for electromagnetic compatibility. However, none of the responses to the EMC questions provided enough information to assess what input and output configurations had been tested or what acceptance criteria were used.
- **General Questions to Assess Vendor Interest and Expected Level of Participation**: All four vendors indicated a strong interest in the program with the intention of performing and maintaining the qualification through their Appendix B affiliate.

Each of the four remaining vendors was invited to, and subsequently attended, a Vendor/User Group Meeting.

Vendors without 10 CFR 50 Appendix B Affiliates

The remaining seven vendors that expressed an initial interest level in the generic qualification project were commercial vendors without Appendix B affiliates in their corporate organization. Six of these vendors expressed enough interest in the program to warrant sending the requirements and screening questionnaire. Of these six vendors:

- Five legitimately evaluated the qualification program and conducted internal discussions with management personnel. These vendors stated that conceptually they would consider working with an outside third-party dedicator.
- Two responded to the requirements and screening questionnaire. One response was quite detailed and rivaled that of the vendors with Appendix B affiliates for level of completion. The other vendor simply checked off which requirements they met; no meaningful responses were provided for the screening questions.
- Four vendors were invited to a Vendor/User Group meeting, however they were advised that they would be at a disadvantage compared to suppliers with nuclear QA programs. At this time it was clear that there were at least four candidate vendors with 10 CFR 50 Appendix B affiliates who could qualify their devices without the need to engage a third-party dedicator. This simplified the screening process and any subsequent qualification activities and represented the best scenario for the nuclear utilities.
- No vendors without 10 CFR 50 Appendix B affiliates chose to attend the Vendor/User Group Meeting.

Results of the Vendor/User Group Meeting

Vendors that completed the requirements and survey questionnaire shown in Appendix B of this report were invited to attend a User Group meeting. The basic purposes of the meeting were to provide an opportunity for the group members to become more familiar with vendor products and to enable vendors to become more familiar with the nuclear market, the project, and what continued participation might entail. The goals for the outcome of the meeting were to provide sufficient information and interchange among the interested vendors, utilities, and project team to enable each vendor to make a final decision on further participation in the project, and for the participating utility engineers to leave the meeting with a better understanding of what each device can and cannot do to help them solve their plant problems.

Four commercial vendors with Appendix B affiliates attended the one-day Vendor/User Group Meeting. All were relatively uninformed with regard to digital technology issues for nuclear plants. The first half of the meeting was spent educating the vendors with information on the qualification and dedication process as applied to digital equipment, along with specific information about the digital valve positioner project and the likely approach that the project would follow. Special attention was given to the qualification activities that have proven most problematic for digital equipment, including the Critical Digital Review and electromagnetic compatibility qualification. The anticipated power plant applications and generic requirements for the digital positioners were also summarized. The participating vendors were allotted approximately 30 minutes each to share information concerning their particular device and their possible approach for qualification and dedication.

The second half of the meeting consisted of vendor presentations to the User Group about the capabilities and features of their devices. All four vendors were present for all vendor presentations. No vendor directly addressed a qualification strategy aside from identifying their Appendix B affiliate that would perform and maintain the qualification.

Feedback from the participating vendors revealed interesting aspects of their perceptions of the meeting. The following is a summary of the major points:

- All vendors indicated that the project team presentations on the generic qualification process, the lessons learned from the previously completed projects, the Critical Digital Review and the unique aspects of nuclear EMC qualification were extremely valuable and should be included in future screening efforts.
- All expressed some level of disappointment in the level of User Group participation. The vendor participants were all responsible for convincing their management that the costs of a qualification program are justified based on the anticipated returns. Evaluating the anticipated market for a nuclear qualified device is a critical step in this cost-benefit analysis. The vendors indicated that they did not learn sufficient information from the User Group to help them complete their market assessment. (This cost-benefit issue has been problematic for nearly every vendor and component that the component qualification project has approached.)
- Several vendors suggested holding two meetings, one for the project team presentations and one for the vendor presentations. They desired to show the User Group members an actual positioner and give them hands-on experience in operating, calibrating, and performing diagnostics on the device.
- One vendor representative indicated that the vendors at the meeting represented the four strongest in the industry and were the ones that he would have picked if he were performing the screening process. This is some indication that the overall process was effective in identifying “best of class” candidates.

Device and Vendor Screening Results for Breaker Over-Current Trip Devices

The above device and vendor screening process, which considered 14 potentially capable digital valve positioners, was adapted to the more limited field of breaker over-current trip devices based on the results of the NMAC User Group survey. An internet search confirmed the four candidate vendors and devices identified by the NMAC User Group, with no new candidates identified. These vendors were contacted to begin the vendor screening process.

Three of the four vendors quickly proved to be impractical candidates for the qualification project, as they had no interest in participating at the time. The fourth vendor emerged as a promising candidate based on preliminary information about their product and their ability and willingness to support a nuclear safety qualification and dedication effort. The candidate vendor does not have a 10 CFR 50 Appendix B quality assurance program within their organization. However, they have an exclusive agreement with an independent third-party dedication company to market and sell their devices to the nuclear power industry. This third-party dedicator has an Appendix B program and was actively marketing the vendor’s over-current trip device and circuit breaker as an integrated product to nuclear industry utilities, with the intent of completing the nuclear qualification activities as part of the procurement activities. Based on their existing plans for qualifying the trip device, the dedicator was interested in working with EPRI for a project following the smart transmitter model as described previously in this report.

The screening process was aided by the fact that a utility belonging to the Component Qualification User Group, in parallel with the project team screening effort, had been evaluating the candidate vendor's device for use in safety related applications at one of their nuclear plants. As part of their evaluation, this utility used the screening questionnaire developed by the User Group in 2002 (Appendix C of this report) to assess:

- the vendor's and dedicator's capabilities,
- the operating history, any experienced failures, and revision history,
- the results of completed qualification testing,
- the trip device's basic design architecture, and
- the processes used for design, manufacture, and testing.

The utility management ultimately cancelled the project, presumably due to resource limitations and regulatory risk. However, the results of their evaluation were shared with the project team and proved to be a valuable part of the screening effort described here.

The complete results of the screening process are fully described in [5]. In short, the screening results looked promising and a decision was made to support key aspects of the qualification effort, principally the CDR, with the third-party dedicator ultimately responsible for the remaining activities. The dedicator would also be responsible for maintaining the qualification and dedication under their 10 CFR 50 Appendix B quality assurance program and providing the component to the nuclear industry as a 1E device.

Device and Vendor Screening Results for Temperature Controllers

The requirements definition process for temperature controllers resulted in a recommendation to expand the previously completed single loop controller qualification projects to meet group needs for a temperature controller. One of the two single loop controllers had already been evaluated for thermocouple inputs based on the needs of one of the User Group utilities at the time of the original qualification effort. This vendor expressed some interest in the project, and discussions were initiated accordingly.

The objective of the screening process was to work with the selected vendor to accomplish the following qualification activities:

- Identify a third-party dedicator willing to take over the previous qualification documentation from EPRI and maintain the qualification into the future, including 10 CFR 21 reporting responsibilities.
- Expand the previous qualification to include resistance temperature detector (RTD) inputs. It was also necessary to evaluate recent software changes to the commercial version of the device to assess whether they should be incorporated into the "frozen" nuclear version.

- Revisit EMC qualification testing to attempt to eliminate an electromagnetic interference (EMI) filter that was inhibitive to the installation environments of most User Group utilities. This filter was required for the controller to successfully pass EMC testing to the nuclear qualification guidelines in effect at the time, and recent changes to the guidelines have provided relief in several key test areas. (See Section 5 of this report for a full discussion on the changes of the nuclear EMC qualification guidelines.)

The vendor ultimately chose not to work further with the project to support qualification and dedication of their controller, presumably because they judge that the business opportunity is insufficient to justify the cost of going forward with the project.

Component Screening Process Lessons Learned

The following is a summary of the lessons learned from the various phases of the screening process, including component selection, requirements definition, and device and vendor screening.

Component Selection Process Lessons Learned

- The most popular candidate components do not necessarily represent the best components for consideration in generic qualification activities from a cost benefit aspect. Additional considerations such as the availability of acceptable 1E analog replacements and the activities of other industry working groups should be considered in finalizing the list of most promising candidates.
- When multiple components are being considered, performing requirements definition in parallel with the component selection process can quickly eliminate unworkable candidates (e.g., radiation monitors where User Group interest was limited to one specific device that was already 1E qualified).
- Activities requiring input or participation from multiple utility engineers can be difficult to arrange and complete in a timely manner, as most are busy with plant activities, outages, etc. While sufficient time should be budgeted in project planning to ensure input is obtained from as many stakeholders as possible, the group should be pushed to provide the necessary information as expeditiously as possible. Interactive technology such as web-cast meetings proved to be a useful tool for conducting gathering such information.
- Utilities prefer candidate components that require minimal field modifications to install. As examples, digital pressure switches were eliminated from consideration, as they would almost certainly require a new cable to route the device power supply, while digital valve positioners were considered favorable candidates, because they all use the existing 4-20 milliamp control circuit as the power supply. Additionally, for temperature controllers, utilities desired pin-for-pin replacements with a device footprint equal to or smaller than that of their existing installations. However, imposing such “non-function-based” requirements can potentially eliminate candidate components that may be superior when qualification and dedication costs are considered.

- For future screening efforts where multiple components are being considered, it is worthwhile to investigate if there are complementary components that are used in nuclear safety related applications (i.e., N-stamped control valves for digital valve positioners). This may lead to finding a component with several vendors that have Appendix B affiliates within their corporation to perform and maintain the digital qualification (i.e., the smart transmitter project model), which has proved to be a desirable approach to generic qualification.
- Although not directly related to component selection, the User Group was requested to provide information about potential third-party dedicators in parallel with completing the component-voting ballot; no information was received. This may indicate a general lack of comfort or experience within nuclear utilities in dealing with third-party dedicators for software based 1E devices.
- Although not strong candidates for the User Group evaluations, radiation monitors and power supplies are clearly components where the nuclear industry desires upgraded devices to address reliability and functionality issues.

Requirements Definition Process Lessons Learned

- Utilities are experiencing obsolescence issues with existing analog I/P devices. Remote operation, calibration, and diagnostics are key features desired from a digital upgrade, potentially resulting in shorter outages, reduced personnel radiation exposure, and cost savings by eliminating reduced power events to troubleshoot the analog devices.
- The requirements definition phase proved to be an extremely important input to the overall screening process. As documented in later sections of this report, this screening process applied to digital valve positioners led to the consideration of a remote mount option for reducing positioner seismic and radiation requirements, and helped to define the need to perform radiation testing as early as possible in the qualification effort.
- Obtaining meaningful results on a requirements survey involves a significant time commitment on the part of those generating the requirements (stakeholders). In many cases, a utility might need time to solicit input from multiple plants or multiple individuals from different departments. For a User Group activity, the survey should only be forwarded to members with a strong interest in a particular device, especially when multiple devices are being considered. A successful approach to completing this phase was to forward the survey to appropriate members in advance of an interview-style conference call, with the project team completing the survey based on answers from the group member.
- The requirements definition phase of the screening process takes a minimum of three to four weeks to develop a consolidated response when multiple components are being considered. This time should be factored into the project schedule for the overall screening process.
- There is no “right answer” to defining a required radiation life for generic qualification. Different utilities have different minimum acceptable replacement intervals based on the dose rate of the intended application, the availability of shielding, and the cost of the device, with acceptable replacement intervals ranging from every outage to three, five or even ten years.

- There is no clear consensus among User Group utilities for requirements for electromagnetic interference testing and evaluation, with a relatively equal number of utilities implementing EPRI TR-102323 Revision 1, EPRI TR-102323 Revision 2, and U.S. NRC Regulatory Guide 1.180. Clearly additional industry-wide projects in this area are warranted.
- The requirements survey should also determine intended non-safety applications for the component of interest. Several utilities indicated a requirement to use a device that successfully completed both EMC qualification and a Critical Digital Review in applications with the potential to impact plant operation (e.g., trip sensitive equipment). In the case of digital valve positioners, utilities were greatly interested in a radiation qualified device for use in non-safety BWR feedwater applications. Information on non-safety applications will also be important in describing the anticipated market to candidate vendors during the vendor screening process.
- The requirements survey did not result in the definition of any concrete requirements for behavior under abnormal or faulted conditions; rather it confirmed the notion that most typical failure modes (e.g., fail as-is, fail to a programmable value, etc.) are acceptable as long as they are known in advance.
- The 2002 User Group screening activities identified “breaker controllers” as a component of high interest to the group for a generic qualification project. However, the term “breaker controller” was not specifically defined by the User Group. This term could refer to an over-current trip device, protective relays, or some other control equipment associated with nuclear plant circuit breakers. The first step in the screening process was to further define the specific needs for a breaker control device, with industry input beyond the seven-member Component Qualification User Group, in order to narrow the scope of potential types of devices and corresponding vendors. Full understanding of specific needs is key to successful screening.
- The screening methodology developed for digital valve positioners, where there were 14 potentially capable devices that could all functionally replace existing analog components, had to be adapted for over-current trip devices, where only four vendors were identified, with each vendor presenting a unique solution for interfacing their equipment to existing circuit breaker installations. While many of the screening principles apply to any device under consideration, the actual methodology should be flexible to address the unique aspects of any particular device and its corresponding market.

Device and Vendor Screening Lessons Learned

Device Screening Lessons Learned

- As most digital devices use some form of external communication protocol, websites from organizations such as the HART® Foundation or Foundation Fieldbus are excellent sources of information about what devices are available. All of the digital valve positioners participating in the project were identified from this website as opposed to from a User Group recommendation.

- Many User Group members indicated a strong preference to work with well known, established vendors with which they had previous operating experience. This is an important consideration. However, unknown vendors should not be categorically excluded and should be evaluated evenly against the entire available field, as they may offer the most favorable solutions when all the life-cycle costs are considered.
- Device screening (i.e., locating specific devices that meet User Group requirements based on available product literature) cannot be effectively performed without some interaction with the device vendor. Consequently, device screening and vendor screening as defined previously in this report are not separable steps in the overall screening process and should be performed in parallel. An initial call to the vendor can help to identify the best candidate component within a vendor's product line, quickly eliminate vendors that do not make compatible devices, and in some cases immediately identify vendors with a strong interest in the generic qualification program or in qualifying and dedicating a device on their own.

Vendor Screening Lessons Learned

- Vendors of capable devices that show an initial interest in generic qualification activities should be pressed to participate in a conference call as soon as possible to elevate information about the program to the decision-making level within the vendor's organization. Conference calls between the project team and key vendor personnel such as engineering vice presidents and national sales managers were conducted for all of the vendors ultimately selected to participate in generic qualification activities; this proved to be a valuable step in convincing the vendors to commit the necessary resources to the project. This reinforces the notion that vendors are more likely to commit the resources for such an effort if they are approached by the utility industry, rather than by individual utilities or power plants.
- The device screening process should not only be looked at as a tool for assessing vendor capabilities. An equally important aspect of this process is to inform vendors about the generic qualification process, the User Group, and the needs of the nuclear industry. A capable device from a vendor with exceptional software development processes is of no use if the vendor declines to participate as a result of not fully understanding the process and the marketplace. EPRI websites, a requirements and screening questionnaire, and documentation on the qualification process, such as EPRI TR-106439, are valuable tools for accomplishing this critical aspect of the screening process.
- The screening process identified several capable devices that are manufactured in foreign countries, with only sales or marketing offices in the United States. The screening process proved to be difficult for these devices because of inaccessibility of supplier personnel due to language barriers and time zone differences. Additionally, the necessary software documentation was in the native language of the country of the manufacturing company. These obstacles can be significant when considering the overall costs and probability of success of a qualification and dedication effort, especially if there are other qualified vendors with devices manufactured in the continental United States.
- While most vendors easily completed the requirements portion of the screening questionnaire (Appendix C of this report), obtaining the desired level of response to the questions about software architecture, software development processes, and qualification testing proved to be difficult. Even the most interested vendors provided somewhat lacking responses to these

questions, indicating difficulties due to time constraints and the number of different people required for thorough completion of the survey, as well as the costs associated with their limited personnel resources. Some vendors may also be unwilling to release sensitive or proprietary information without first entering into a non-disclosure agreement. A suggested approach in future screening efforts is to arrange interview-style conference calls with the device software developers and CDR experts shortly after forwarding the vendor the survey questions. This would alleviate the need for vendor personnel to write the survey responses, and the open conversation would likely provide additional insight into these areas in question.

- The above considerations, however, do not take away from the overall value of the requirements and screening questionnaire. Not only did the software-related screening questions inform vendors about the nature and complexity of the program they were considering entering, in many cases it served to quickly screen out vendors who simply did not want to deal with the difficulties associated with nuclear qualification. Thus the questionnaire proved to be an effective screening tool.

- Setting the date of a Vendor/User Group Meeting as a deadline for responding to the requirements and screening questionnaire was an effective method for pushing serious vendors to complete this survey.

- Most of the 14 devices that were seriously evaluated by the project met the basic functional requirements defined by the User Group. This is an indication of the strong capabilities of modern digital products. The devices selected as finalists in the screening process were more a function of the level of interest and the capabilities and characteristics of the vendor and their processes, rather than the capabilities of the device itself.

- Although no vendors without 10 CFR 50 Appendix B affiliates chose to attend the Vendor/User Group Meeting, there was a surprisingly large number that expressed interest in nuclear qualification and actively inquired to learn about the process. One vendor even contemplated starting a 10 CFR 50 Appendix B program within their company to support the project. This may provide some insight into the future level of participation of commercial vendors in nuclear industry projects. Also, many suppliers are adopting ISO 9000 QA programs, and at some point the nuclear commercial grade dedication process may be able to credit such programs to make it much easier to engage non-Appendix B suppliers.

- The Vendor/User Group Meeting proved to be a vital step in educating vendors about nuclear requirements and what is involved in the generic qualification process. All vendors indicated that they learned enough to effectively estimate the scope, costs and resource requirements for nuclear qualification as an input to their decision making process.

- User Group participation such a meeting is vital, because the vendors are typically struggling to make the case that there is a viable nuclear market; every effort should be made to have at least as many group attendees as vendors present. The User Group should give the vendors an appropriate audience to justify the time and effort for them to prepare for and travel to the meeting. This is a crucial aspect of helping the vendor representatives develop their strategy for justifying participation in a qualification program to their management.

- For future Vendor/User Group meetings, all vendors should be present for the project team presentations on the generic qualification process and for User Group requirements and application discussions to ensure each is exposed to the same information. However, if logistically possible, the vendor presentations to the User Group should be conducted without their competition present. This will be advantageous to both the User Group and the vendor, as they would likely present more detailed technical information.

- For future Vendor/User Group meetings, ensure vendors are aware that their competition will be present. This fact should be conveyed verbally in addition to being documented in an invitation letter.
- The screening process from initial vendor contact to the time of the Vendor/User Group Meeting took three months. In retrospect at least two months are necessary to progress through these steps. The extra month was mostly a result of keeping the door open for indecisive vendors to ensure that each was given a fair chance to participate. It is important to balance the need for fairness against the need to move the project forward. In this case, three of the four finalists that attended the User Group meeting were obvious top choices within a week of initial contact. The fourth attendee, who became a serious candidate towards the end of the three-month period, ultimately withdrew from consideration due to resource constraints. Thus a shortened process would have yielded identical results.
- Discussions with device vendors revealed significantly different design approaches in regard to utilizing digital over-current trip devices for plant upgrades. Some of the digital devices are an integral part of a replacement breaker and thus require breaker replacement for a digital upgrade. In this case, the replacement breaker was designed to replace some of the most common, but not all existing circuit breakers. Other digital over-current trip devices were designed to be utilized with some, but again not all, existing circuit breakers. In this regard, the current designs of digital over-current trip devices do not allow as much flexibility for applications compared to other evaluated devices (single loop controllers, smart transmitter, and valve positioners) which are designed as stand alone replacements and are essentially interchangeable with various models manufactured by competitors.

3
QUALIFICATION STRATEGY

A key lesson from the pilot projects was that generic qualification should include consideration of how the qualification of the device will be maintained in the long term. Experience has demonstrated that fully commercial vendors typically do not want to take on responsibility for maintaining a nuclear program because nuclear customers are a small part of their business. On the other hand, a company that has a division with a 10 CFR 50 Appendix B program may be willing to maintain the qualification of a commercial division's product using their nuclear quality assurance program.

This lesson was successfully applied to the qualification and dedication projects for digital valve positioners and the breaker over-current trip device. For both types of component, the qualification and dedication project would be performed, documented, and maintained by an affiliated company or third-party dedicator with a 10 CFR 50 Appendix B program. The project would provide support during the initial qualification effort in key areas to augment the vendor's and dedicator's capabilities.

This section describes the strategy employed for the valve positioner and breaker trip device generic qualification projects and the associated lessons learned. It also discusses the strategy for and lessons learned during the Model 375 Field Communicator evaluation.

Digital Valve Positioner Qualification Strategy

Determining Vendor and Project Team Responsibilities

For each selected equipment vendor, an early step was to determine the division of qualification activities between project team and the vendor. Since the selected positioner vendors are N-stamped valve suppliers, they al ready had well-developed processes in place for the traditional "shake and bake" environmental qualifications performed for typical hardware qualifications. These activities were picked up by the vendors, and the project team focused on the digital equipment issues that were new and unfamiliar to the vendors, and for which EPRI has been developing guidance and interacting with the regulator for the last several years. Thus, the project team led the Critical Digital Reviews (CDRs) and performed independent reviews of the existing commercial EMC testing certifications (typically CE mark testing per European standards) against the nuclear industry's accepted electromagnetic interference (EMI) guidelines, taking advantage of the connection to the EPRI EMI Working Group. The vendors took responsibility for all other necessary qualification activities under their affiliate company's 10 CFR 50 Appendix B program, including radiation, seismic and supplemental EMC testing, as well the commercial grade survey, identification and verification of critical characteristics and all other commercial grade dedication activities. The vendors would continue to maintain and update the qualification and dedication in the event of future design changes and would be responsible for Part 21 reporting. Finally, the project team offered additional support and guidance to help vendors through the qualification process.

This model for splitting up the evaluation and qualification activities was particularly useful to the project, because it took advantage of existing vendor and project team expertise, ensured that the latest guidance on digital upgrades was applied, and helped keep the vendors engaged, despite technical and cost-benefit concerns. The project had the additional advantage that it effectively could approach the vendors as an industry, rather than an individual plant or utility. Still, this model for splitting up the activities may also be useful for a utility working with a preferred supplier to qualify and dedicate needed equipment.

Critical Digital Review

The strategy for performing the CDR incorporated a lesson learned from the smart transmitter qualification by obtaining and reviewing as much CDR documentation as could be made available in advance of the formal site visit to the vendor's facility. This preliminary review, called a "Pre-CDR," would conclude with a recommendation on continuing with the site visit and would thus be used as a decision point for going forward with the process. If the preliminary review revealed significant deficiencies that could impact the success of the qualification program, then the effort could be reconsidered with minimal impact on EPRI and vendor resources.

Radiation Testing

The utility requirements survey yielded no clear requirement for a minimum qualified radiation lifetime, with a wide range of potential dose rates and desired replacement intervals varying from every outage to ten years. To address this variance, the qualification strategy called for performing radiation "fragility" testing, or testing to device failure, rather than attempting to qualify a specific radiation life.

A key feature for the digital valve positioners under consideration was their capability to remotely mount the positioner (including microprocessor and pneumatic relays) away from the valve. In this configuration, only the valve position sensor is directly mounted on the valve. This offers the advantages of locating the microprocessor and other electronic and pneumatic components in areas of lower radiation or in areas where shielding can easily be installed. The remote mount configuration is typically used to isolate the sensitive positioner components from vibration or high temperature conditions at the valve and to reduce the repair cost if these valve conditions cause the position sensor to fail. The radiation qualification therefore called for fragility testing of both the standard mount and remote mount configurations to give utilities maximum flexibility for their specific applications. Radiation testing would be performed by the vendors, with review of test requirements and acceptance criteria by the project team.

Seismic Testing

Based on a lesson learned from the single loop controller project, the qualification strategy called for performing seismic testing at the Seismic Qualification Reporting and Testing Standardization (SQURTS) test laboratory. The pneumatic valve components in the digital valve positioners were a source of concern as to whether the devices could survive the bounding, 14g peak SQURTS spectrum. Similar to radiation testing, the remote mount configuration offers the advantage of locating most of the seismically sensitive components away from the valve and thus in a milder seismic environment. The qualification strategy therefore called for seismic fragility testing of both the standard mount and remote mount configurations. Seismic testing would be done in accordance with the applicable nuclear industry standards, and the project team would again provide support in reviewing test plans, requirements, and acceptance criteria.

EMC Evaluation

It was recommended that each vendor's commercial EMC test reports be reviewed against the nuclear industry guidance documents for EMC qualification. The scope of the review would include a comparison of the applicable tests, frequency ranges, test levels and acceptance criteria against nuclear requirements, as well as an evaluation of the input and output configurations tested against those intended to be included in the qualification. The review would focus on whether any commercial testing could be credited for the nuclear qualification. A key concern was whether the remote mount option was included in the commercial tests, as this was an option desired by both the User Group and the vendors.

As a lesson learned from the single loop controller qualifications, it was also recommended that informal EMC scoping testing be considered to find and remedy problems before the formal Appendix B qualification testing. The informal tests would address specific areas that were not covered in the commercial EMC certification, such as expanded frequency ranges, higher test levels, and additional input and output configurations, with the goal of assessing device performance and troubleshooting potential problems before performing expensive formal qualification testing.

Sequence of Activities

The strategy for determining the sequence of qualification activities centered on performing the activities with the most uncertain outcome first to minimize risk (i.e., spending time and money on an ultimately unsuccessful candidate) for both EPRI and the vendors. For valve positioners, the CDR and radiation testing were judged to be the biggest unknowns. Seismic and EMC testing were seen to have a lower risk, because these devices often operate in industrial environments with some vibration, and the selected vendors had already performed some EMC testing. The results of the CDR might limit the recommended applications for a specific device, and the qualified radiation life would define the required replacement interval for a given plant application. The results of these two activities are key factors for utilities in deciding to install the device in their plants and for vendors in determining their available market prospects. As such, the strategy called for performing the Pre-CDR and radiation testing first and in parallel, to the extent possible. As discussed above, the formal CDR site visit would follow based on a positive recommendation from completion of the Pre-CDR.

Circuit Breaker Over-Current Trip Device Qualification Strategy

Similar to the valve positioner vendors, the third-party dedicator for the selected over-current trip device also had the “shake and bake” capabilities associated with typical hardware qualifications. However, the dedicator also had experience with performing qualification testing to the applicable nuclear qualification guidelines, as well as preparing a dedication package. As such, the strategy for the breaker trip device qualification effort used project team support only for the CDR. The strategy also included performance of a Pre-CDR as a decision point for going forward with the full CDR site visit.

The vendor of the circuit breaker over-current trip device is represented by a U.S. distributor, but the design, test, and manufacturing facilities are located in France. This presented potential difficulties with language barriers and with the timing of communications, due to the eight-hour time difference between project team members in California and designers in France. These issues were mitigated by assigning to the project an engineer who is fluent in both French and performing CDRs. A preliminary evaluation was also performed at the vendor’s U.S. facility to preview some design documentation.

Initially, four similar models of trip device, all within the same product line, were considered for inclusion in the qualification project. However, the review team determined that there was not a great enough demand for the features offered in the more complex models to warrant the increased scope and detail needed to complete their evaluation. The reviewers determined that a qualification project involving these models would likely be successful if an adequate level of evaluation was performed.

Model 375 Field Communicator Evaluation Strategy

The Model 375 Field Communicator is not intended for use in safety related applications and will only be used with equipment that is not being credited with a safety function, so it will not be qualified or dedicated. However, it will be used as a support tool for maintenance, diagnostics, testing, calibration, configuring, and installation of safety related equipment. The tool needs to be evaluated (as the 275 was evaluated) to ensure that it will not cause safety related devices to fail to perform their intended functions. The strategy for this evaluation involved a Pre-CDR and CDR that were limited in scope. No qualification testing was necessary for the Model 375, since it is designed for industrial use and can only be used when a technician is present.

The Model 375 will replace the HART® 275 Handheld Communicator as the preferred support tool for use with the smart transmitter and all of the valve positioners considered by this project. It was designed by the same organization that designed the smart transmitter and the Model 275 (Emerson Process Management), and the evaluation would be maintained by the same 10 CFR 50 Appendix B affiliate.

Qualification Strategy Lessons Learned

The following is a summary of the lessons learned from developing an evaluation or qualification strategy where the vendor, through an affiliated division with a 10 CFR 50 Appendix B program or a third-party dedicator with a 10 CFR 50 Appendix B program, will perform the majority of the qualification activities and ultimately own and maintain the qualified product. Note that some of the lessons that validate the strategy presented above are based on the success of actual qualification activities and are presented in later sections of this report.

- For projects with commercial vendors with affiliated divisions that have a 10 CFR 50 Appendix B program, or third-party dedicators with an Appendix B program, EPRI (or utility) resources are best applied to areas of unique expertise, particularly the CDR. The CDR proved to be the biggest unknown to the vendors and an area where the third-party dedicator welcomed the project team's expertise and experience.

  With the Model 375, the vendor had already undergone a CDR for the smart transmitter and the previous Model 275. While the design organization and the Appendix B affiliate were well prepared for the CDR, had incorporated the recommendations from the previous evaluation, and understood the process of the CDR, they were not comfortable with performing a CDR on their own.

- The participating vendors were agreeable to the proposed qualification strategy. A general conclusion from the screening process through the development of this qualification strategy is that vendors who agree to enter this type of project already have an understanding of the nuclear industry and the associated market for their product and were looking for ways to enter that market. Supporting these vendors through performance of the CDR and by providing advice and guidance in other areas of the qualification proved to be enough of an incentive for them to commit resources to a nuclear qualification effort. Alternately, indecision seems to indicate that the vendor cannot quite justify spending the resources needed to complete the effort.

- That being said, it may be helpful to provide assistance to the vendors to support informal EMC testing or utility member sponsored SQURTS seismic testing. Anything that can be done to reduce a vendor's out-of-pocket expenses will increase the likelihood that a capable vendor will agree to participate. In some cases, these or other incentives may be necessary to make it possible for the vendor to justify devoting resources to the small, uncertain nuclear market.

- Commercial vendors, and in some cases even their affiliated companies with 10 CFR 50 Appendix B QA programs, are generally unfamiliar with nuclear EMC testing requirements. EPRI or utility support in this area may be helpful to assist the vendors in determining the level and extent of testing required and in preparing for actual qualification testing. The vendors themselves, however, are well suited to perform the actual testing, as they have extensive knowledge of the characteristics of their devices. On the other hand, third-party dedicators who routinely perform component qualifications are more familiar and thus less likely to need assistance in the EMC area.

- Use of a Pre-CDR is an effective means to minimize financial risk for both the CDR reviewers and the vendors.

- Unique device capabilities should be considered when developing a qualification strategy. For digital valve positioners, including the remote mount option in the scope of the qualification minimized the radiation and seismic environmental constraints on the device, resulting in many more potential applications and thus a greater market for the vendors.
- To reduce risk during a qualification project, activities with the most uncertain outcome should be scheduled first. The planned schedule should attempt to strike a balance between mitigating potential risks and progressing with a desirable schedule for qualification activities. For the case of digital valve positioners, performing the Pre-CDR and radiation testing in parallel achieved this objective, requiring commitment of both project team and vendor resources and providing early indications to all stakeholders (EPRI, User Group members, and the vendor) that the project would result in a device that could be used in desired plant applications. This lesson is particularly applicable to generic qualifications, but can also apply to a specific qualification, where a utility contracts a third-party dedicator to qualify a component for their unique plant requirements.
- There is no clear single answer for a qualified radiation lifetime for a digital component. Plant radiation environments vary widely, and utilities indicated minimum desirable replacement intervals varying from every outage to ten years. For generic qualification projects, “fragility” testing, or testing to device failure, rather than attempting to qualify a specific radiation life or test level, may help maximize the potential applications of the device.
- The circuit breaker over-current trip unit project initially included four models of varying complexity. One lesson learned from the initial pilots was to consider device complexity during the screening process. Although the project team was not able to assess the complexity of each unit during screening, the team determined that the CDR might be focused on one or two of the simpler units, due to resource limitations and lack of User Group interest in the advanced features.

4

CRITICAL DIGITAL REVIEWS

For the single loop controller qualification and dedication project, the project team performed both the Critical Digital Review (CDR) and the commercial grade survey. The smart transmitter project differed in that the project team performed the CDR in parallel with the vendor's 10 CFR 50 Appendix B affiliate performing the commercial grade survey. The lessons learned from the pilot projects' CDRs, documented in [1], relate to:

- Preparing the device designer personnel for the types of questions that will be asked and why they are important to nuclear applications.
- Review team preparation for the CDR, developing a full understanding of the device functionality and theory of operation, as well as the planned applications and their requirements.
- Technical capabilities of the review team in the design, development, and application of digital instrumentation and control equipment.
- Planning for potential shortcomings revealed during the CDR, including the scope of operating history reviews and the strength of the vendor's commercial practices.
- Coordination of the CDR with the commercial grade survey.

Critical Digital Reviews for the digital valve positioners and the trip device followed the smart transmitter model, with the project team performing the CDR, but not the commercial grade survey. For the Model 375 Field Communicator, the project team performed a CDR that was reduced in scope. Before each CDR, the project team completed a Pre-CDR based on the lessons learned from the pilot programs [1]. The following is a discussion of the CDR process and the associated lessons learned as applied to digital valve positioners, trip devices, and the Model 375.

Working with the Commercial Vendors

At the start of the qualification project, most of the commercial vendors were unaware of the purpose and scope of a CDR. The screening process in Section 2 of this report described significant efforts to educate vendors about this process by providing relevant technical guidelines and holding conference calls with the planned CDR technical reviewers.

In some cases, the nuclear division of a vendor's company was eager to join a qualification and dedication project, but the device developers, in a separate instrumentation division, were hesitant to commit the necessary resources. One vendor had recently expended significant resources on a certification project to achieve Safety Integrity Level 3 using IEC 61508 (for emergency shutdown applications) and did not want to engage in another such time consuming activity.

The Pre-CDR strategy, described below, was an effective tool for addressing this vendor concern. Following this strategy, reviewers can get a strong insight into the device architecture and the vendor's design process with the only commitment from the vendor being the time necessary to generate a non-disclosure agreement and to gather and transmit the necessary documentation. Following an advance review of this documentation, the project team can typically accomplish the objectives of a CDR in a two-and-a-half to three-day site visit for a device with similar complexity to a smart transmitter or digital valve positioner. The project team successfully conveyed this strategy to the vendors and the parties reached agreement to perform the preliminary CDRs.

For the trip device dedicator, the facilities for the U.S. distributor, and the design, testing, and manufacturing groups are distributed across the U.S. and in France. Different sets of device and process documentation are located at each of the facilities, which have a variety of corporate and national cultures. All parts of the organization seemed to be willing to support the qualification and dedication project, but coordination and planning were still difficult with this many involved groups. The CDR was performed in stages, with some aspects of the full CDR covered by a reduced review team visiting the U.S. distributor's site.

Preliminary CDR

In accordance with the qualification strategy described in Section 3 of this report, a preliminary CDR was performed to provide confidence that a full site visit was warranted. After executing non-disclosure agreements, the vendors supplied available documents based on a request for the following generic documents applicable to their specific product:

- Quality assurance manuals
- Hardware and software design procedures
- Test plans and procedures
- Peer review procedures
- Results of tests and peer reviews
- Handbooks or guidelines for design and testing
- Results of independent third party reviews
- Design specifications for parts of the design as well as the complete device
- Owners' and Installation manuals
- Software release history (including the versions released, date of each release, and number of units sold per release)
- A list of user contacts for use in a review of the device's operating history

For the completed Pre-CDRs the reviewers concluded that, despite several areas requiring attention and possibly resulting in compensatory actions, there was a reasonable likelihood of success for the qualification and dedication effort and that the projects should proceed with the formal CDR site visit.

Summary of Pre-CDR Results

The following are some of the key observations from the Pre-CDRs. Most of these are typical of what is anticipated for a commercial vendor new to 10 CFR 50 Appendix B software development.

- Vendors responded differently to the request for Pre-CDR documentation, depending on the maturity of their software development group and part of the organization that dealt with the project team directly. Some vendors considered some of the requested documentation to be too sensitive or proprietary to be released for a Pre-CDR and withheld these until the formal site visit; others provided nearly the entire list of requested documents.
- Many commercial vendors expected the CDR reviewers to be overly critical, believing there would be a need to create new procedures, or even revise their products, to meet nuclear expectations. Vendors were hesitant to release documentation that they believed might not meet reviewer expectations. In several cases, the reviewers had to reassure the vendors that a lack of documentation would not necessarily cause them to "fail" the qualification project, and that although compensatory actions might be required, the overall success or failure of the effort would be based on a "preponderance" of available evidence. The project team reassured the vendors that the goal was to qualify the existing device based on this evidence, as opposed to creating a new or "frozen" nuclear version. Creating a custom product for the nuclear industry is exactly what the project wanted to avoid; it would not be "commercial grade dedication." Additionally, the custom design might invalidate useful operating history and restrict future upgrades.
- In general, the design documentation created and kept for the valve positioners was not as thorough as it would be for a device developed under a nuclear quality assurance program. Documentation was especially sparse for the early stages of development, because they were developed in the mid-1990s, when software development processes were still relatively immature in all industries. Software documentation has improved over time, with the increasing maturity of the software developers and development processes. The documentation of the Model 375 Field Communicator and the circuit breaker over-current trip device was more detailed, suggesting that these vendors have more established development processes.
- The project team reviewed the quality assurance manuals of the Appendix B organizations performing the nuclear qualification activities for the digital valve positioners. The valve positioner vendors' manuals were designed for the qualification and dedication of hardware and analog electronic components and did not apply to software-based devices. The project team recommended to the vendors that they review their quality assurance manuals to determine whether they should be modified to address software-based devices. While this activity is not required for completion of a CDR, vendors would ultimately have to undertake this effort in order to pass a NUPIC audit to be able to sell their devices as a 1E component to nuclear utilities. The project team did not review the quality assurance manuals for the trip device dedicator or the Appendix B affiliate for the Model 375. It is expected that both manuals apply to software-based devices, since both organizations have performed qualification activities for software-based devices in the past.

CDR and Operating History Review

Based on the positive recommendations from the completed Pre-CDRs, the full Critical Digital Reviews and Operating History Reviews were performed following the guidance contained in EPRI TR-106439 [2] and EPRI TR-107339 [3].

A lesson learned from the pilot qualification and dedication projects was to attempt to perform the commercial grade survey in parallel with the CDR, with a goal of having a matrix of critical characteristics prepared before the CDR site visit. This lesson was based primarily on the single loop controller qualification and dedication project where the device capabilities far exceeded the basic functionality that was considered critical characteristics. Many of the software capabilities of the controllers, including feed-forward control, manual control mode, and proportional plus manual reset control mode, were not included in the bounds of the project and were therefore not fully evaluated during the CDR. The controllers also had capabilities to handle multiple types of inputs and outputs (RTDs, thermocouples, 1-5 volt, 4-20 milliamp, etc.) that were not all included in the qualification.

The hardware and software of the digital valve positioners is almost entirely devoted to controlling a pneumatic output based on the desired input signal and the position feedback from the valve. Similarly, the software and hardware of the evaluated trip devices is primarily devoted to performing the trip function. In these cases nearly all of the software was evaluated within the scope of the CDR. As a result, defining critical characteristics in advance of the CDR was not as relevant for the valve positioners' and trip device's qualifications.

However, determining which features would be used by the utilities was useful in determining which models and features should be evaluated. This helped the project team focus the trip device qualification on two models instead of four. Knowing the utilities' needs and desires also helped the project team identify unessential features that would not be evaluated during the digital valve positioners' CDRs (e.g., the position indication output), which resulted in recommendations not to use those features.

For all completed CDRs, the conclusion was that in regard to the issues investigated in the CDR (failure modes, unanticipated behaviors, software architecture, etc.) the devices would be acceptable for use in nuclear safety related applications, subject to certain recommendations for use, and that future versions of the device software would also be acceptable so long as the software development and maintenance processes were at least as good as the processes evaluated. This was obviously preferable to the outcome of the single loop controller CDRs, where the software version evaluated at the CDR was "frozen" as the nuclear version.

A key goal of the CDR process was for the vendors to learn enough to be able to address future software changes themselves. For the valve positioners, the trip device, and the Model 375 Field Communicator, the vendors, dedicators, and Appendix B affiliates will be entirely responsible for demonstrating the acceptability of future software versions. This could be achieved once the vendor passed a NUPIC audit that included the development and revision of safety related software based devices within the scope of the audit.

As part of the digital valve positioner CDRs, the reviewers also evaluated use of the HART® 275 Handheld Communicator and the vendors' proprietary diagnostic and configuration software (which also use the HART® communication protocol), and concluded that (from the CDR perspective) they would be acceptable for use as support tools for the testing, calibrating and configuring the positioners. The Model 375 Field Communicator CDR similarly concluded that the Model 375 would be an acceptable tool for performing the same functions that the Model 275 previously performed. The CDR report *for the Model 375* has been written such that the nonproprietary conclusions could be extracted and sent to the valve positioner vendors for incorporation in their dedication packages.

Summary of Key CDR Results

The following is a summary of some of the key results of the CDRs and Operating History Reviews performed in this project. Many of these observations can be generally applied to other commercial digital devices developed in the last 10 years.

- Original releases of the devices were typically not developed under rigorous, formal design control processes, which would be more characteristic of today's processes. Newer releases were developed under enhanced processes, as the vendors' software processes have evolved.
- For the current device releases, vendors conducted comprehensive, formalized, and well documented testing. This included regression testing and validation that errors found and corrected in earlier versions are not present and reintroduced into the product. Testing for the new releases was driven by product requirements, with acknowledged inclusion of changes in requirements. The CDR review of the testing did not identify requirements for additional Functional or Challenge Testing, but the commercial grade surveys may generate such requirements.
- The digital valve positioner development processes relied heavily on testing, with varying levels of peer review of the device software. In general, the reviewers found that vendor peer reviews, and the level of independence of these reviews, did not meet expectations for a device designed under a 10 CFR 50 Appendix B program. In some cases, recommendations were made for additional peer reviews of future software changes. Mitigating this finding was the fact that few software design defects have been uncovered, with most being limited to obscure code for unusual configurations.
- The Model 375 Field Communicator design processes and documentation were more thorough than those of the valve positioners, with the level of quality consistent with expectations for a device developed under a nuclear quality assurance program. This is partly attributable to the fact that the software design group responsible for the Model 375 had already completed a CDR for the smart transmitter and Model 275 efforts and had incorporated recommendations from that project. This group had also enhanced their processes recently to achieve Level 2 of the Software Engineering Institute's Capability Maturity Model.
- The design documentation for the circuit breaker over-current trip device was even more detailed and comprehensive than the documentation for the Model 375. In fact, reviewers noted that the commercial vendor's processes were more rigorous than those used by some nuclear quality assurance programs. It is likely that this vendor has adopted this level of quality to meet European standards for devices used in high integrity applications.
- In some cases, the sound design practices actually in use were not documented in the engineering procedures, resulting in recommendations to modify procedures to reflect the actual practices employed.

- Vendors maintain tight quality control over their suppliers, supporting the expectation that supplied components will be free of defects.
- Some vendors outsource portions of the hardware and software embedded in their products. In such cases, it may be necessary to evaluate the processes, documentation, and design of the outsourced software or hardware. The dedicator or Appendix B affiliate needs to be able to ensure that all aspects of the design are of adequate dependability for the intended high integrity or safety related application. As with the CDR, this evaluation should determine whether the current design can be accepted and whether the subcontractor's processes are adequate to accept future revisions to the design.

Critical Digital Review Lessons Learned

- When engaging commercial vendors to participate in a joint qualification and dedication project, it may take several weeks or months (elapsed time) to educate them about the CDR process and what it entails. Providing nuclear industry guidance documents and coordinating conference calls with experienced CDR reviewers will help achieve this objective. Many vendors expected the CDR reviewers to be overly critical, resulting in vast changes to their processes or products. They felt that the time commitment to get through the CDR process would not be achievable within their resource limited schedules.
- The Preliminary CDR strategy proved to be effective, not only as a risk mitigating measure as described in Section 3 of this report, but as a way of maximizing the efficiency of the full CDR by focusing on critical issues and questions from the preliminary review. This also minimizes the time commitment required by the vendor's design and development organization.
- The valve positioner CDRs confirmed the previous lesson learned to expect shortcomings in the design and development processes and the associated documentation as compared to the requirements of a 10 CFR 50 Appendix B program for digital devices. The reviews also confirmed that most failure modes prove to be acceptable if they are known, well documented, understood, and evaluated prior to application in the plant.
- For Appendix B vendors that are not experienced in the design of digital devices, it should be expected that their quality assurance manuals will need to be updated before the device can be sold as a 1E component. This should be discussed during the screening process and clearly communicated to the vendors.
- Similarly, the Pre-CDR, if not the screening process, should attempt to determine if the vendor outsources any part of the software development for its device. This could prove to be a hurdle to completing a nuclear qualification, as it may necessitate additional interactions with the contracted third-party developer, including non-disclosure agreements, additional CDR site visits, etc.
- A desired result of the CDR process is the conclusion that the software version evaluated, as well as future software versions developed under similar processes that are at least as good as the processes evaluated, are acceptable for use in nuclear safety related applications. To avoid necessitating a "frozen" nuclear version, the vendor will be responsible for demonstrating the acceptability of the future software versions. This can only be achieved if the vendor has in place or initiates a formal program that can successfully pass a NUPIC

audit that includes development and revision of software-based devices within the scope of the audit. To succeed at this audit, the vendor should implement any corrective actions identified during the CDR and should also understand the CDR process well enough to be able to conduct similar evaluations on their own for future changes. These considerations should be clearly communicated to vendors during screening as well as during the qualification and dedication processes.

- For relatively simple devices, it may not be necessary to combine the commercial grade survey with the CDR, particularly when the survey is the responsibility of the vendor. However, it is valuable to understand which features of the device are considered critical and which features could be considered non-critical.
- The circuit breaker over-current trip device project marked the first application of the CDR process to a digital device based on an application specific integrated circuit (ASIC) instead of a microprocessor. Most CDRs focus on the quality of the software design and processes for a device that uses a standard microprocessor, with a less rigorous evaluation of the hardware design; the expectation is that the microprocessor has a significantly larger operating experience base and that the hardware design can be tested to a greater extent than software. In this qualification project, the reviewers focused their evaluation more on the hardware design and quality of the ASIC, since it is only used in this application. This shift of priorities is not detailed in TR-106439 or TR-107339, but the reviewers found the process to be analogous to the traditional CDR.

5
EMC QUALIFICATION

Electromagnetic compatibility (EMC) qualification in the pilot qualification efforts for the single loop controllers proved to be problematic. The testing was performed in accordance with the guidelines given in EPRI TR-102323 R1 [6], which was the accepted industry EMC guideline at the time the test program was initiated. The results were consistent with other data available at the time, which indicated that digital devices were not likely to meet the TR-102323 R1 requirements unless they were specifically designed to meet those requirements. This means that most, if not all, commercial digital devices would need some form of mitigation (additional filtering, shielding, etc.). The number of failures that occurred in the initial testing to TR-102323 R1 requirements, the extent of mitigation and additional testing ultimately required to meet those requirements, and the difficulty in general of performing the tests in accordance with the standards, even when working with a competent commercial test lab, all exceeded initial expectations. These efforts proved to be significant contributors to the overall cost and schedule of the digital device qualification project and were seen as a potential risk for future projects.

The lessons learned from the pilot efforts, documented in [1], relate to:

- Careful selection of the device, considering what vendor testing has already been performed to industry standards (CE Mark testing, tests to meet European EMC Directives, etc.),
- EMC hardening of test equipment,
- Use of informal testing to identify vulnerabilities and design appropriate mitigation before attempting formal compliance tests,
- Application of newer EMC guidelines, which relax test requirements and test levels from those of TR-102323 R1.

The digital valve positioners' EMC qualifications differed from those of the single loop controllers in that the device vendors were responsible for the testing, while the project team provided support and guidance, as described in Section 3 of this report. However, most of the above lessons remain applicable. The following is a discussion of the above lessons as applied to digital valve positioners, as well as new insights from the valve positioner EMC qualification efforts.

Evaluation of Commercial EMC Test Results

All of the digital valve positioners in the generic qualification program had previously undergone some form of commercial-level EMC testing and had the CE mark showing compliance with the European EMC Directive. The vendors provided their test reports for review by the project team to evaluate if any of the commercial testing could be credited and thus to determine the extent and scope of the EMC testing needed for the nuclear qualification effort. The following are some observations from review of commercial EMC test reports:

- In many cases, the commercial test reports did not clearly define the test setup and configuration. For example, most digital valve positioners include an optional 4 to 20 milliamp output signal to transmit the valve position. Test reports did not indicate if a cable was connected to this output during conducted susceptibility and emissions testing.
- Commercial test reports often do not clearly document acceptance criteria. As an example, one positioner was tested for electrical fast transients to the same test levels required by nuclear qualification guidelines. The acceptance criteria for the test allowed momentary degradation during application of the transient so long as the device continued to operate as intended after the test. The test report indicated that the device passed, however it did not indicate whether any temporary degradations in performance were observed. Momentary degradations in performance may not be acceptable in some Class 1E applications; explicit documentation of the test results would have been beneficial for the assessment of the device's EMC vulnerabilities.
- In one case a test report did not define the test levels applied for high frequency conducted susceptibility testing.
- Commercial EMC emissions testing is generally not directly comparable to nuclear qualification testing. Commercial testing often does not include conducted emissions as required by nuclear qualification standards. Radiated electric field emissions testing is included in the commercial tests, however the frequency range did not cover that required by nuclear qualification standards, and testing is often conducted in an open air test site rather than in a shielded enclosure.
- Commercial radiated electric field susceptibility testing generally does not cover the entire frequency range required by nuclear qualification standards.
- Commercial EMC tests often do not include surge withstand capability testing as required by nuclear qualification standards.

These observations lead to the general conclusion that additional EMC testing to nuclear standards will likely be required beyond the commercial testing, even if the device has the CE mark. However, upfront review of the commercial test reports still proved to be a worthwhile activity in predicting device performance and gaining some level of confidence that the device could pass nuclear qualification testing. This review will also identify areas that should be tested during informal scoping testing as described below.

EMC Hardening and Complexity of Test Equipment

The single loop controller EMC qualification used a personal computer-based Automated Test System (ATS) to stimulate the controller, simulating a process variable to allow the controller to operate in a closed loop. The ATS provided a time-varying 4 to 20 milliamp remote setpoint input to the controller. It monitored the controller 4 to 20 milliamp output signal, and computed a process variable that was fed back as a 4 to 20 milliamp input to the controller. Additionally, it monitored two digital output signals from the controller. The ATS was programmed to alarm if the computed process variable deviated from the desired setpoint by a certain threshold, or if the controller digital outputs cycled from the expected value during the test, signaling a failure.

Protecting this test equipment from the electromagnetic interference (EMI) disturbances being applied to the controller proved to be a difficult challenge in the pilot qualification effort. Significant effort was required to "harden" the test system, resulting in additional time and cost at the test laboratories. In the initial testing of single loop controllers, analysis of the results indicated that some apparent susceptibilities of the controllers may have been due to ATS vulnerabilities.

The digital valve positioner qualification effort successfully incorporated this lesson from the pilot qualification. In addition to protecting the test equipment with appropriate EMI filters, the project team recommended that the test setup be kept as simple as possible to avoid introducing false susceptibilities to the positioners. In one vendor's test setup, the input signal was driven by an analog 4 to 20 milliamp signal generator. The valve positioner was connected to a rotary actuator fitted with an angle indicator and a rheostat on the stem. Valve position was monitored visually with a video camera and electrically with an ohmmeter on the connected to the rheostat. This simple test setup proved to be sufficiently protected from the EMI disturbances applied to the positioner, thus eliminating many of the difficulties experienced during the single loop controller EMC qualification effort.

In summary, digital valve positioner testing confirmed the lesson that test equipment should be adequately protected from the EMI disturbances. In addition, it demonstrated that test equipment should be kept as simple as possible within the limitations necessary to meet testing and data collection requirements.

Use of Informal and Formal Testing

The single loop controller EMC qualification efforts demonstrated the benefit of conducting informal "shake out" testing prior to formal qualification under QA controls. It is expected that most commercial digital devices will show some susceptibilities when exposed to the test levels called for in the nuclear qualification guidelines. Troubleshooting and implementing design changes (e.g., additional shielding or EMI filtering) during formal QA testing is both cumbersome and expensive.

This lesson was validated during the digital valve positioner EMC qualification effort. Informal testing was performed, focusing on potential vulnerabilities identified from review of vendor commercial EMC test reports. This testing proved invaluable, identifying the need for additional EMI filtering to meet nuclear qualification test levels for high frequency conducted susceptibility, fast transients, and surges. The filter design was finalized during this informal testing, allowing the vendor to incorporate it into the product design prior to performing formal EMC and seismic testing. The filter design was validated when formal EMC testing was successfully completed with no further design modifications required.

A second lesson from the single loop controller EMC qualification effort was that informal scoping testing should be conducted at the same test laboratory, if possible, that will perform the formal qualification testing. This lesson was based on difficulties associated with debugging the test setup (i.e., ATS equipment, connectors, patch panels, power supplies, grounding provisions, filter components) during the formal testing. These issues did not occur during the digital valve positioner qualification, even though two different labs were used. This is attributed to the simplicity of the valve positioner test setup as compared to that of the single loop controllers. Thus, the lesson from the pilot qualification to use the same lab for informal and formal testing may not apply when the test setup is reasonably simple.

Application of New EMC Guidelines

The single loop controller EMC qualification testing was performed in accordance with the guidelines given in EPRI TR-102323 R1 [6], which was the accepted industry EMC guideline at the time the test program was initiated. The controllers required extensive EMI filtering to meet the test levels specified in TR-102323 R1. In fact, the filter assemblies were significantly larger than the controllers, which effectively eliminated the controllers from consideration for most intended nuclear plant installations.

At the completion of the pilot qualification programs, two additional guidelines were issued, Regulatory Guide 1.180 [7] and Revision 2 of TR-102323 [8]. Both of these guidelines provided some relief from the requirements of TR-102323 R1. At the start of the 2002 screening effort, however, it was apparent that Revision 2 of TR-102323 would not receive a Safety Evaluation Report from the NRC. Additionally, the NRC issued Revision 1 to Regulatory Guide 1.180 [9] shortly before the start of digital valve positioner qualification activities. This was the guidance document used for the valve positioner EMC testing.

Revision 1 to Regulatory Guide 1.180 provides relief to the test requirements of TR-102323 R1 in several key areas:

- **High Frequency Conducted Susceptibility**: Eliminates testing above 30 MHz (provided that high frequency radiated susceptibility testing is performed), and reduces the test level for power lines. It also provides a separate, even lower test level for low power signal lines, which were not separately specified in TR-102323 R1.
- **High Frequency Radiated Susceptibility**: Eliminates testing below 30 MHz (provided that high frequency conducted susceptibility testing is performed).
- **Surges and Electrical Fast Transients**: Reduces test levels by 33% for "low exposure" installations (i.e., those expected for valve positioners).

These changes from TR-102323 R1 are reflected in the size of the EMI filter components necessary for the digital valve positioners to pass the R.G. 1.180 Revision 1 test levels. One filter consisted of a simple resistor-capacitor-inductor circuit to mitigate susceptibilities to high frequency conducted EMI, and metal oxide varistors as additional protection against surges and electrical fast transients. Whereas the single loop controllers required an external filter mounted in a 12" by 12" enclosure, the valve positioner filter components were able to be mounted to the existing device housing, making the filter essentially transparent to the utility user.

EPRI TR 102323 Revision 3 was published in November 2004 as EPRI Report 1003697. This revision proposes lower levels for high frequency conducted susceptibility testing (CS114) based on reassessment of the data and analysis used to establish the original levels in TR-102323, and on better aligning the nuclear plant test requirements with military and industry standards.

EMC Qualification Lessons Learned

Many of the lessons learned from the single loop controller EMC qualification were successfully applied to the digital valve positioner qualification, as evidenced by the successful EMC qualification of a positioner with minimal additional filtering. The following is a summary of the additional lessons learned from the valve positioner EMC qualification effort.

- Commercial EMC testing generally is not sufficient for a nuclear safety qualification. Emissions test requirements do not align with the nuclear requirements and susceptibility test levels are lower in many cases. Also, test reports are often not detailed enough to be able to confirm all desired configurations of the device were tested. However, the results can be valuable for identifying potential vulnerabilities that should be evaluated during informal EMC scoping testing and for assessing likelihood of success of a nuclear qualification.
- A simple test system, while still meeting data monitoring and collection requirements, will minimize problems with test set up and will minimize the probability of falsely detecting susceptibilities to the device under test. The simplified test system may also alleviate the constraint of performing informal and formal testing at the same test laboratory.
- Informal scoping testing proved to be extremely helpful and cost effective, compared to finding and correcting problems during formal testing under an Appendix B QA program. It can reveal design flaws or the need for additional filtering, and can quickly confirm adequacy of prototype fixes, which can then be fully designed and incorporated into the device prior to both formal EMC and seismic testing.
- The digital valve positioner project confirmed that commercial vendors are capable of conducting nuclear EMC qualification testing once they are sufficiently educated on the unique test requirements and test levels required for the nuclear industry. Competent EMC test labs often have test engineers who can help write test plans, define acceptance criteria, and assist in troubleshooting.
- The digital valve positioner projects also reinforced the value of the smart transmitter model. The vendors should be more familiar with the installation practices and troubleshooting than any other party. A failed attempt by the informal test lab to install one device illustrated the need for the vendor to update their installation instructions with more detail.
- The evolution of nuclear industry EMC guidelines, which relax some requirements, is apparent in the reduction of filter size from the single loop controllers to the digital valve positioners, both of which were commercially tested to similar test levels (CE mark). However, the continued need for additional filtering shows that commercial grade devices are not typically designed for the EMC needs of the nuclear industry.
- High frequency conducted susceptibility testing continues to be a problem area for most commercial digital devices. The latest EPRI guidance on the issue, TR-102323 Revision 3 [10], published in November 2004, proposes relaxed testing levels that should help alleviate the problem.

6
OTHER QUALIFICATION TEST LESSONS

In the single loop controller pilot qualification program, the project team conducted all qualification testing, including baseline, seismic, EMC, and functional and challenge testing, with no direct involvement from the device vendors. Many of the lessons learned documented in [1], such as determining the number of necessary test specimens or choosing the frequency of baseline testing based on cost and risk considerations, do not necessarily apply to this project, since the vendors are responsible for all of the qualification test activities.

Three lessons from [1] do apply, and they were successfully applied to the valve positioner effort. Specifically:

- If qualification testing will be performed for more than one component, significant savings can be realized by performing these tests simultaneously. If multiple devices successfully complete testing, this may provide a "diversity" option if needed for specific utility applications. Alternatively, if a device does not complete the test successfully, it can be eliminated from consideration.
- Seismic testing performed using standardized generic test specifications and procedures at a test laboratory under contract with the utility SQURTS group is cost effective and efficient.
- Because supplemental filters are likely to be required to enable a commercial device to meet nuclear EMC qualification requirements, EMC testing should be conducted prior to seismic testing. Seismic testing could then be performed on both the device and supplemental filter(s). Inclusion of a filter in the seismic test adds little to the cost of seismic qualification, if anything.

The following is a discussion of the digital valve positioner qualification testing, specifically radiation and seismic testing, and the associated lessons learned. EMC testing is not discussed here as it was previously discussed in Section 5 of this report. As noted in Section 3, the project team did not provide support for qualification testing of the circuit breaker over-current trip device or the Model 375 Field Communicator.

Radiation Testing

The requirements definition phase of the digital valve positioner screening process yielded no clear single answer for a qualified radiation lifetime for digital valve positioners. Plant radiation environments vary widely, and utilities indicated minimum desirable replacement intervals varying from every outage to ten years. To address this variance, the qualification strategy called for performing radiation "fragility" testing, or testing to device failure to attempt to maximize the potential applications of the device. In accordance with the qualification strategy, the project team supported vendor radiation testing by providing guidance for the test setup and configuration, reviewing test specifications prior to submittal to the test laboratory, and reviewing laboratory test plans.

The test setup took advantage of the valve positioner remote mount capabilities and incorporated a lesson learned in [1] by testing both direct mounted and remote mounted configurations simultaneously. This setup provided results for the maximum total integrated dose (TID) to failure for both the positioner electronics, including the microprocessor, and the separate remote mount valve position sensor. This information will provide utilities with maximum flexibility for their specific installations, allowing optimization of replacement intervals for the remote position sensor and electronics module based on the known radiation levels at their respective installation locations.

Test results confirmed the expectations for the dose to failure, demonstrating a radiation life on the order of 10^3 rad for the electronics and at least 10^6 rad for the remote mount position sensor. These results should yield acceptable replacement intervals for most of the applications desired by the utilities of the user groups.

This activity clearly demonstrates the benefits of defining clear functional requirements before initiating a generic qualification and dedication project. Utility desires for the remote mount capabilities were conveyed to the valve positioner vendors during the screening process, and were thus included in the qualification, with successful results.

Another interesting aspect of the radiation qualification testing is that it creates opportunities to use the digital valve positioners in non-safety related applications that require a qualified radiation lifetime. One key example is for feedwater control applications in boiling water reactor plants. Utilities identified a strong need for this application during the screening process. In fact, many utilities would also want the feedwater control valve positioner to have gone through an EMC qualification and the CDR for this operations-critical application where device failure could trip the plant. This presents vendors with interesting opportunities to market their devices for specific applications with varying levels of qualification and appropriately adjusted pricing.

Seismic Testing

In keeping with the qualification strategy, a utility sponsored seismic testing for a valve positioner under the SQURTS program. The project team also provided support to coordinate and develop the seismic test plans with the test lab and facilitated conference calls to coordinate the details of the test configuration and setup.

The SQURTS seismic test plan was developed to address both available configurations of a positioner. The standard seismic test requirements of IEEE 344 were used for basic testing. In addition, RIM testing to the requirements of IEEE 382 was performed, because the positioner or position sensor must be mounted to an actuator and valve for testing. For the remote mount configuration, only the position sensor, actuator, and valve were placed on the RIM table, while the positioner was located off the table. The standard mount configuration was tested at the same time, with another positioner and an integral position sensor mounted to a second actuator and valve. Following RIM testing, random, multiple-frequency testing to the requirements of IEEE 344 were required at table limits (14g). First, the positioner was tested alone (i.e., part of the remote mount configuration) using five tests at the operating basis earthquake (OBE) level, which is 70% of the safe shutdown earthquake (SSE) level. Upon completion of the OBE testing, one SSE level test was performed on all parts of both configurations: the actuator with positioner and integral sensor (direct mount), the actuator with valve position sensor (remote mount), and the independent positioner (remote mount).

The device under test included a finalized design of the EMI filter that was developed during the informal EMC scoping testing. All test configurations successfully passed the seismic and functional testing, including enveloping all RIM seismic requirements and maintaining full operability during RIM and triaxial random multi-frequency SSE table limit tests.

Qualification Testing Lessons Learned

- Qualification testing is more likely to go smoothly when the designer or vendor is directly involved in the testing, whether through the Appendix B affiliate or a third-party dedicator. The vendor best understands the technical capabilities and functionality of their device, installation procedures and details, how to monitor it during testing, and how to implement any necessary changes to the design (e.g., mounting hardware, EMI filtering) as a result of qualification test failures. The valve positioner project did not have to address many of the issues faced in the single loop controller qualification (described in [1]), such as procurement and control of test articles and being able to easily obtain additional devices if one were damaged during qualification testing. In short, this confirms the lesson learned to attempt to follow the smart transmitter qualification model.
- Vendors should be made aware that the typical qualification project may result in a number of products to suit a range of users. For example, a device could be sold without the full qualification package for non-safety related service, but with an EMC qualification report and a published radiation susceptibility level. This level of qualification may be sufficient for valve positioner use in non-safety related boiling water reactor feedwater systems for many utilities. Nuclear qualifications tests and evaluations might even be leveraged for use in other high integrity applications, such as the medical or military fields. This may provide more incentive for vendors to perform these qualification activities, if the product can be introduced into different applications with appropriately adjusted pricing.
- Radiation and seismic qualification testing confirmed the lesson previously stated in Section 3 related to taking advantage of a device’s unique capabilities in developing a qualification strategy, and confirmed the need to define device requirements prior to initiating qualification activities. For the digital valve positioners, including the remote mount option in the scope of the qualification will minimize the radiation and seismic environmental constraints on the device, resulting in many more potential applications for the utilities and thus a greater market for the vendors.
- Vendors were able to reduce the cost and risk of testing by including both configurations in their qualification tests, confirming the lesson learned from [1] that similar devices should be tested together when possible. Utilities that are beginning qualification projects may consider performing a critical qualification test for several devices as a final step in the screening process. Purchasing and adding one or two extra devices to a test adds a nominal cost to that test, but this may be outweighed by the risk of pursuing a qualification project for a device that will ultimately fail to meet utility needs.
- The digital valve positioner qualification and dedication project confirmed the lesson from [1] that some form of EMC testing should be conducted prior to seismic testing. In this case, informal EMC testing, which identified the need and provided the opportunity to design an appropriate EMI filter, was performed first. The subsequent seismic testing included the EMI filter fully incorporated into the device electronics housing. If seismic testing were conducted before the EMC scoping testing, the seismic tests would likely have to be repeated with the EMI filter included.

- This project confirmed the lesson from [1] regarding the benefits of performing seismic testing at the SQURTS test laboratory. The SQURTS laboratory has many standardized test specifications and procedures (including ones for single loop controllers and valve positioners) that simplify and streamline the seismic qualification process.

7
CONCLUSIONS

This section of the report revisits the lessons learned from the initial pilots, documented in [1], to assess whether they were reinforced or modified by the subsequent qualification and dedication activities, and presents an overall summary of the most significant lessons learned from the generic qualification effort to date. It also discusses a common issue throughout both the digital valve positioner screening and qualification effort, specifically the nuclear market for these devices and the associated effect on the vendors involved in the project.

Confirming the Lessons Learned from Initial Pilots

A goal of this project was to incorporate the lessons learned from the pilot qualification projects into the screening methodology and subsequent qualification efforts for the selected devices and vendors. The following is a summary of the applicable pilot qualification lessons from [1] and whether they were confirmed or modified by the activities of this project:

Lessons from Selecting Devices and Vendors

- ***Lesson:*** Look at the entire picture when evaluating costs, beyond the purchase price of the device.

  Result – Confirmed: Purchase price was not a significant factor in the screening process. The cost of each qualification and dedication effort pursued in this project (project team and vendor efforts combined) is estimated to exceed fifty times the cost of a unit of any evaluated device.

- ***Lesson:*** Consider the degree to which commercial qualification testing already performed can be used to demonstrate compliance with nuclear qualifications.

  Result – Confirmed: Successful candidates had the CE mark for EMC, and test results from independent laboratories confirming device specifications and documenting device performance under abnormal or faulted conditions.

- ***Lesson:*** Evaluate what measures may be required to "harden" or extend the device capabilities beyond commercial specifications to meet nuclear qualification requirements.

  Result – Confirmed: Successful candidate device specifications generally met the User Group needs. The vendors were not asked to redesign their devices or attempt to validate better specifications, as this would likely be unattractive to most vendors and could invalidate parts of the qualification and evaluations, particularly the operating history assessment.

- ***Lesson:*** Consider the complexity of the device including internal architecture, external interfaces, and built-in software.

Result – Confirmed: The evaluated digital valve positioners are relatively simple devices, with one microprocessor (ranging from 8-48 kilobytes of code) and simple input and output configurations. The valve positioner CDR site visits required three days, which is towards the shorter end of the scale for common digital devices.

Four models of a circuit breaker over-current trip device were evaluated in this project, with a range of additional features and corresponding complexity. Eventually, the review team decided to eliminate the two most complex models from the qualification project, because the level of interest in the User Group did not justify the required level of effort needed to fully evaluate those models. The trip device was designed by a French company, using an application specific integrated circuit (ASIC) to perform the primary trip functions. The CDR process had never been used to evaluate this type of device, but the reviewers were able to complete the on site CDR in about four days, even with the language barrier.

The Model 375 Field Communicator is perhaps the most complex device evaluated in the current project, having several microprocessors and much more software code than the valve positioners. It was the first device evaluated to rely on a commercial embedded operating system (Windows® CE). However, the evaluation was limited in scope to verify only that the device would not cause the undetected failure of a safety related device.

- ***Lesson:*** Consider the relevance, extent and success of the device's commercial operating history.

  Result – Confirmed: The screening process determined the extent but not the relevance or success of operating history. One of the valve positioners evaluated had over 30,000 devices in the field with no major new software releases over five years. This was viewed as a positive in the screening process. The relevance and success of the operating history were evaluated during the operating history survey performed in conjunction with the CDR and contributed to the successful outcome.

- ***Lesson:*** Evaluate the level of involvement and cooperation of the vendor in the qualification effort, including their willingness to support a CDR, implement a design "freeze" for the nuclear model if necessary, and their willingness to commit resources to the qualification effort in light of the expected return for their investment.

  Result – Confirmed: The valve positioner finalists expressed a strong corporate commitment to complete the nuclear qualification, and pledged to support a CDR and "freeze" the design if determined to be necessary (it was not necessary for the most recent CDRs). The trip unit dedicator and the Model 375 vendor are both driven to complete their projects in order to meet their customers anticipated needs.

Lessons from Project Planning

- ***Lesson:*** For a generic qualification effort, obtain end user input in establishing the basic functional requirements and the desired features, functions, and configurations for the device.

  Result – Confirmed: The requirements definition phase determined a solid set of requirements to be forwarded to the vendors and proved to be an extremely important input to the overall screening process. This screening process applied to digital valve positioners led to the consideration of a remote mount option for reducing positioner seismic and radiation requirements, and helped to define the need to perform radiation testing as early as possible in the qualification effort. For the trip device, knowing the value of selected features helped the project team determine which models should be evaluated.

- ***Lesson:*** Avoid special requirements that apply only to specific plants or applications. Also, avoid use of configurations that are not in accordance with the manufacturer's recommendations.

  Result – N/A: Additional requirements beyond the manufacturers' published specifications were not introduced; screening activities were based on these specifications and User Group needs. Defining the allowable operating configurations and limitations for use is the vendor's responsibility when following the smart transmitter model with an Appendix B affiliate running the qualification. The vendors were encouraged to use existing specifications as critical characteristics, since the commercial manufacturer's process will continue to ensure that the published specifications are met, but may not have special provisions for other requirements. A successful one-time test of a special requirement does not ensure that future devices will meet that requirement.

- ***Lesson:*** Document the specific features and configurations to be qualified at the start of the qualification effort to ensure a common understanding among all stakeholders.

  Result – Confirmed: The project team worked with the vendors to determine which device hardware and software options should be included in the generic qualification program.

- ***Lesson:*** Define in advance the performance criteria to be applied to the device during qualification testing, such as transient response to surges or a momentary loss of power, necessary failsafe states, etc.

  Result – Modified: These aspects of the qualification testing were the responsibilities of the vendors under a project following the smart transmitter model. In general, the requirements were to maintain performance in accordance with the device's published specifications. This original lesson derived from the single loop controller project where the capability to maintain closed loop control was not clearly defined in the device specifications, and the requirements could vary significantly between different intended applications. Valve positioners and trip units differed in that accuracy requirements are clearly specified. The valve positioner efforts did demonstrate that most failure modes (e.g., response to transient loss of power) prove to be acceptable if they are known, understood, and evaluated prior to application in the plant. Also, actual behaviors under "failed" conditions could be documented as limits of the qualification, so that users of the device could assess their impact in the intended application.

- ***Lesson:*** Address quality assurance issues and interactions between the various parties involved in the qualification (e.g., EPRI, EPRI contractors, vendors, third-party dedicators).

  Result – Confirmed: Non-disclosure agreements and special purchase order arrangements were needed. In some cases, difficulties associated with executing non-disclosure agreements with three or four involved parties caused delays in the project.

- ***Lesson:*** Define as clearly as possible the scope of any mitigation efforts that will be applied if device malfunctions are encountered during qualification testing.

  Result – Confirmed: During the screening process, it was conveyed to the vendors that modifications or additional EMI filtering would likely be necessary for the devices to successfully pass EMC qualification testing. This prediction proved to be accurate for digital valve positioners, with no other modifications necessary during the qualification effort.

- ***Lesson:*** Consider how the qualification of the device will be maintained in the long term.

  Result – Confirmed: The preferred arrangement follows the smart transmitter model, using the vendor's Appendix B affiliate or dedicator to perform and maintain the qualification and dedication. For the devices selected for project support, each type of component had at least one vendor with an Appendix B affiliate or dedicator, which simplified the screening process.

Lessons from the Commercial Grade Survey and Critical Design Review

- ***Lesson:*** Vendor materials should be provided to the review team before the visit, to allow the team adequate time to familiarize themselves with the device or system and with the vendor's development plans and procedures.

  Result – Confirmed: Conducting the Pre-CDR in advance saved time during the on-site visit and minimized the impact on vendor personnel.

- ***Lesson:*** Design review personnel should fully understand the device functionality and theory of operation, the planned applications and their requirements, and should be thoroughly familiar with the guidance provided in EPRI TR-106439 and EPRI TR-107339.

  Result – Confirmed: The reviewers were experienced in performing CDRs following the guidance of TR-106439 and TR-107339, which contributed to the success of the project. The reviewers prepared for all CDRs by reviewing the User Group requirements, vendor literature, and Pre-CDR documentation. In most cases, the reviewers that performed the Pre-CDR were also involved in the CDR

- ***Lesson:*** The review team should discuss the minimum requirements for device functionality and behavior under off-normal conditions, and any requirements for error detection, self-diagnostics, and fault tolerance.

  Result – Confirmed: The CDR reviewers used the requirements defined by the User Group as input to the CDR process to ensure the appropriate functionality was included in the scope of the CDR.

- ***Lesson:*** Expect that the CDR will reveal some shortcomings in design and development processes and associated documentation when compared to the requirements of a 10 CFR 50 Appendix B program for digital devices, and look for supplemental activities to compensate.

  Result – Confirmed: The design documentation created and kept for the commercial valve positioners was not as thorough as might be expected for a device developed under a nuclear quality assurance program. Compensating activities included successful operating history and comprehensive testing.

  The processes and documentation used for the Model 375 and the trip device were significantly more rigorous than those used for the valve positioners. This is partially attributed to the fact that both vendors have increased the quality of their design and test practices to meet industrial standards for developing devices for high integrity applications. Additionally, one vendor had previously hosted a CDR for another product and had incorporated the process and documentation recommendations from that effort.

- ***Lesson:*** Expect that designers of the device may be defensive when discussing what may be perceived as shortcomings in the design, fault tolerance or behavior under error conditions, or in the processes used to develop the product.

  Result – Confirmed: A common theme from the Pre-CDR process was that the commercial vendors expected the CDR reviewers to be overly critical, believing there would be a need to create new procedures or even to revise their products to meet nuclear expectations. In several cases the reviewers had to reassure the vendors that a lack of documentation would not necessarily cause them to "fail" the qualification project, and that, although compensatory actions might be required, the overall success or failure of the effort would be based on a "preponderance" of available evidence. Additionally, the reviewers reassured the vendors that the goal was to qualify their existing device and accept their revision processes based on this evidence, as opposed to redesigning a custom, "frozen" nuclear version.

- ***Lesson:*** The planning of the survey and CDR should include consideration of the various organizations who will be involved, their QA programs, and the issues that may be involved in transfer of information among organizations and how these will be handled.

  Result – Confirmed: Non-disclosure agreements between the involved parties were required to be implemented prior to the vendor providing the Pre-CDR documentation or allowing site visits. Additionally, the vendors were required to place the EPRI contractor on their Approved Supplier Lists to be able to accept the CDR report as a 10 CFR 50 Appendix B evaluation and include it in the dedication package.

- ***Lesson:*** An initial matrix of the critical attributes and proposed methods of verification should be developed prior to conducting the commercial grade survey and CDR.

  Result – Modified: For relatively simple devices such as digital valve positioners and circuit breaker over-current trip devices, it may not be necessary to combine the commercial grade survey with the CDR, particularly if the survey is the responsibility of the vendor. However, it is still important for the reviewers to understand which characteristics of the device are considered critical and which features are not necessary or desired.

Lessons from EMC Qualification

- ***Lesson:*** The amount of previous EMC testing to commercial standards should be considered when selecting a device for generic qualification.

  Result – Confirmed: The valve positioners selected by the screening process all had the CE mark for compliance with European EMC directives. This provided some level of assurance of a base level of EMI ruggedness.

- ***Lesson:*** New EMC guidelines provide relief from some of the requirements of EPRI TR-102323 R1.

  Result – Confirmed: The valve positioner EMC testing was conducted in accordance to Revision 1 of Regulatory Guide 1.180, which specifies lower test levels for the high frequency conducted susceptibility test, the most problematic test for the single loop controllers. Future guidance may provide even more relief in this area.

- ***Lesson:*** Special test equipment should be "hardened" against the EMI levels planned for the qualification testing.

Result – Modified: The valve positioner EMC qualification testing included filtering to protect the test equipment from the applied EMI. However, the simplicity of the test setup played the more significant role in eliminating many of the difficulties experienced during the single loop controller qualification.

- ***Lesson:*** Perform informal "shake out" testing prior to formal QA testing to aid in verifying the test setup, gain an understanding of device vulnerabilities, and design any necessary filtering to eliminate the vulnerabilities.

  Result – Confirmed: For the valve positioners, informal testing demonstrated the need for additional EMI filtering for the high frequency conducted susceptibility, surge and electrical fast transient testing. The filter design was finalized and incorporated into the device, which successfully passed formal QA testing with no other difficulties.

Other Qualification Test Lessons

- ***Lesson:*** If qualification testing will be performed for more than one component, significant savings can be realized by performing these tests simultaneously. If multiple devices successfully complete testing, this may provide a "diversity" option if needed for specific utility applications.

  Result – Confirmed: Not only does this lesson apply to qualification activities, but to screening activities as well. The decision to work with three digital valve positioner vendors resulted in an economy of scale in developing the qualification strategy and resulted in comparing "apples to apples" when ranking the four finalists. The vendors benefited during qualification testing by including both standard and remote configurations in the test, and from receiving identical recommendations and general support from the project team. Since test labs primarily bill clients based on the amount of time spent in the lab, simultaneously testing several devices can be much more cost effective than testing each individually. Utilities may consider performing a critical qualification test (i.e., radiation) with several candidate devices at the end of the screening process, to help make a final screening decision.

- ***Lesson:*** The SQURTS group provides a standardized and cost effective approach for seismic qualification testing.

  Result – Confirmed: This proved to be a desirable option for the valve positioner vendors to minimize their project costs. The trip device dedicator already had the contacts and expertise to perform independent qualification testing, and the Model 375 Field Communicator did not require qualification testing.

The Digital Valve Positioner Nuclear Market

Throughout the 2002 screening process and the resultant 2003 qualification support projects, the valve positioner vendors repeatedly asked about the expected market for nuclear qualified digital valve positioners. The vendors must make judgments on how many positioners they can expect to sell and at what price, so that they can justify the capital investment for the qualification effort. This data was likely a key consideration in each vendor's decision to join the qualification effort, and the lack of this information likely caused some of the delays experienced in launching qualification activities.

In response to these questions, a short survey was prepared and distributed to the utility members of this Component Qualification User Group and the Air-Operated Valve Users Group (over 400 recipients). The following is a summary of the significant observations from the results of the survey:

- Of the more than 400 people polled, thirteen responses were received, representing nine utilities and twenty-eight nuclear power plants in the United States and Canada. Three of the respondents were valve positioner vendors requesting information regarding the generic qualification effort. All ten of the utility respondents (two responses from one utility) indicated some interest in qualified digital valve positioners.
- The predicted number of digital valve positioners needed ranges from zero to thirty-eight devices per unit for the twenty-eight units represented, with an average of about 15 positioners needed per unit. The ten utility respondents predict a need for approximately 405 devices at their plants over the next four to ten years. The first orders are expected to be placed between this year and 2005.
- Several of the responses suggested that more digital valve positioners might be purchased as replacements to failed analog positioners, depending on their reliability and availability.
- Several of the respondents have had experience with commercial digital valve positioners in non-safety related service. These users site trouble with performance, reliability, and ease of configuring the new devices.

The overall level of response from the AOV User Group was somewhat disappointing, and the potential market is judged to be somewhat greater than what the survey response indicates. It appears that utility representatives are hesitant to respond to such surveys when they do not have approved, funded upgrades in progress that will need the equipment. However, they often acknowledge that such equipment will be needed at some point, and they could better serve themselves by providing such information to vendors to help ensure that a supply of qualified components will be available when needed. For suppliers of components of this type, the nuclear power industry represents such a small part of their business that it is often difficult to attract their interest, and to a large extent vendor participation may ultimately hinge on the level of interest that utilities show in such surveys. It should also be noted that direct contact by utilities with a vendor concerning the need for a particular device is another effective tool in convincing a vendor to commit resources for qualification activities. As an example, one vendor's decision to participate in the project was influenced by interested utility members who approached the vendor at an AOV industry conference regarding the project and use of their positioner in safety related applications.

Final Conclusions – Insights and Lessons Beyond the Initial Pilots

Perhaps the most prominent overall conclusion that can be drawn from this screening effort and subsequent qualification activities is that they confirmed the benefit of approaching vendors as an industry through organizations like the Component Qualification User Group, rather than on a utility-by-utility basis. Pooling utility resources and sharing the economic risks allowed a thorough investigation and a "best of class" solution, rather than premature selection of a specific device, resulting in an increased risk of problems during the qualification and dedication activities. It also made participation far more attractive for the equipment suppliers, who were able to interact with a group of utilities, receive expert guidance on and assistance with the qualification activities, and minimize the risks associated with the qualification and dedication process. Without the group approach, it is likely that some vendors would have chosen not to participate.

The following is a summary of some of the most significant lessons as applied to the overall screening and qualification and dedication effort:

- When pursuing a "best of class" solution for a given component as described in this report, implementing a formal screening methodology is beneficial to the overall success of the project. This was demonstrated by the success of the screening effort as applied to digital valve positioners, specifically:
  - The group successfully defined the vital functional requirements for these components as well as the additional desired features that could be included in the qualification.
  - The screening process effectively conveyed the unique aspects of nuclear qualification to the vendors, eliminated those who were not serious, and resulted in four strong candidates at the Vendor/User Group meeting. One vendor attendee indicated that he thought that the four vendors in attendance represented the four strongest valve positioner vendors in the industry.
  - The finalists selected all have a capable device and Appendix B affiliates within their companies to execute and maintain the qualification and ultimately sell the positioners directly to the utilities as 1E devices. Additionally, they all expressed a strong interest and commitment to completing nuclear qualification.
  - At the time of this report one digital valve positioner vendor has successfully completed all qualification activities with acceptable results for most intended utility applications.
- This screening process and subsequent qualification efforts confirmed the desirability and benefits of working with commercial vendors with Appendix B affiliates, following the smart transmitter project model. This project model is beneficial from four main considerations:
  - The vendors perform and fund many of the qualification and dedication activities. This is particularly useful during qualification testing, because the vendors best understand the technical capabilities and functionality of their devices, how to install and monitor them during testing, and how to implement any necessary changes to the designs as a result of qualification test failures.
  - The vendors will maintain the qualification into the future. They will be responsible for fault and failure tracking, Part 21 reporting, and reviewing and incorporating device modifications and updates.
  - The vendors become more educated about the unique aspects of nuclear qualification, especially with the software considerations covered in a critical digital review, to the point where they will be able to perform additional commercial device qualifications on their own in the future.
  - The vendor will sell the device directly to utilities as a 1E component with a generic qualification and dedication package suitable for all U.S. nuclear plants. Utilities will not need to perform a separate dedication.

- However, to realize these benefits, the nuclear power industry could do more to help encourage Appendix B affiliated vendors to enter into generic qualification projects. This could involve:
  - Informing the vendors about the nuclear industry requirements and the unique aspects of nuclear generic qualification to ensure they fully understand the process that they may embark on. This may be accomplished through conference calls, requirements and screening questionnaires, and industry guidelines such as EPRI TR-106439.
  - An equally if not more important area is helping the vendors to understand the potential market and thus the potential return on their investment from participating in the program. All of the digital valve positioner finalists indicated that they performed market studies after the Vendor/User Group Meeting as a necessary step in convincing their management that participation in the program was warranted. All finalists also indicated that they did not get the information that they desired or expected in this area. In the future, it may be helpful to enlist the support of various industry groups (e.g., AOV Users Group, NUPIC, JUTG, NMAC Breaker User Group) to work with commercial suppliers to help them engage the nuclear industry.
  - Finally, the industry should continue looking for opportunities to reduce vendor costs through utility sponsored qualification activities such as SQURTS seismic testing or informal EMC scoping testing at utility test facilities.

In summary, when trying to find Appendix B affiliated vendors to enter a joint qualification project, the screening process should focus on the vendor needs as well as the needs of the nuclear industry and the User Group.

- This screening process also confirmed the difficulties in working with commercial vendors that do not have Appendix B affiliates. These vendors generally had less knowledge of the nuclear industry and its unique requirements, and therefore were less likely to commit significant resources to support it. Several of the more interested vendors expressed concern about legal hurdles they would have to overcome to even consider a nuclear-related project. Additionally, the need to locate a third-party dedicator to perform and maintain the qualification adds another level of complexity to the screening process. Finally, it appears that there is a general level of discomfort or lack of experience among the User Group members in working with third-party dedicators for qualification of digital software-based components. This lesson was confirmed by the temperature controller screening effort, where the single loop controller vendor ultimately chose not to work further to support qualification and dedication of their controller.
- The cancellation of a utility project to qualify and dedicate a digital breaker over-current trip device indicates there is still industry reluctance to independently invest in or accept the risk of qualification and dedication projects for digital devices. However, the desire of the Component Qualification User Group to proceed with qualification of the same device through the project confirms the need for these types of devices in the industry.
- Obsolescence not only affects aging analog equipment, but digital equipment as well, as commercial vendors incorporate new features into their products based on the needs of the controls industry as a whole. The HART® 275 Handheld Communicator is now obsolete and has been replaced by the Model 375 Field Communicator. The 275 was evaluated about five years ago as part of the smart transmitter qualification and dedication, and was relied on for

the digital valve positioner CDRs as part of this project. Similarly, one of the valve positioner vendors decided that a successor to the model evaluated during the screening process would be more appropriate for nuclear qualification. Developments in the digital industry provide further evidence that qualification and dedication of a device is an ongoing process dependent on changing technology. In fact, digital equipment typically becomes obsolete much faster than analog equipment, which means that qualification and dedication of such equipment is not a one-time event. Vendors and their Appendix B affiliates or dedicators need to be able to maintain and update their qualifications to support commercial device revisions. Additionally, an efficient, cost-effective process for digital device qualification will continue to be needed by the industry.

- This project confirmed the benefits of working with various additional industry user groups, specifically the AOV User Group, the NMAC Breaker User Group, the SQURTS User Group, and the EPRI EMI Working Group, to improve the efficiency and value of generic qualification efforts.

8
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9. USNRC Regulatory Guide 1.180 Revision 1, "Guidelines for Evaluating Electromagnetic and Radio-Frequency Interference in Safety Related Instrumentation and Control Systems," October 2003.
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A

GENERIC REQUIREMENTS SURVEY

Component Qualification User Group
insert specific device Requirements Survey

Name:________________________ Organization:________________________

Instructions for User Group members

- This survey form is only for the ***insert specific device***. Different survey forms will be used for the other three device types selected by the User Group.
- Please respond to the following questions, providing as much information as possible. Your responses will be combined with those from the rest of the User Group members to attempt to bound the applications and requirements for the ***insert specific device*** to be considered for the generic qualification process.
- For device requirements, indicate which features are "must haves" and which are only "desired."
- This survey consists of the following sections:
  - I. Application Information – defines the intended applications for the ***insert specific device*** at your plant(s), including safety significance and economic risks.
  - II. Physical Requirements – defines requirements for installation, I/O configuration, communication capabilities, power supplies, etc.
  - III. Performance Requirements – defines requirements for accuracy, response time, environmental ratings, response to fault conditions, etc.
  - IV. Specific Digital Devices – allows you to provide input as to which specific vendors and devices you would or would not consider for qualification.
  - V. General Comments – this section is used to provide any additional information that does not relate to a specific question in this survey that you feel is relevant to the qualification of the ***insert specific device***.

I. Application Information

1. Are there safety related applications in your plant where a generically qualified ***insert specific device*** could be used to perform equivalent functions?
☐ Yes ☐ No
If yes, how many different applications do you foresee using the ***insert specific device*** in? ________
Do all have the same level of safety significance? Please describe.

2. For each safety related application of the ***insert specific device***, please provide the following information: (see next page for space for additional applications)

2.a. **APPLICATION A**: Is the intended use a new application or a replacement of an existing device?

☐ New Application
☐ Replacement If a replacement for an existing device, is the existing device analog or digital? ☐ Analog ☐ Digital

How many ***insert specific device*** will be required for this application? ____________

What plant system(s) is the application a part of?

Are there any interfaces of the device with other plant systems?

Describe the specific application. Will the device be used to increase the functionality of a current application? If so, how?

2.b.	**APPLICATION B**: Is the intended use a new application or a replacement of an existing device? ☐ New Application ☐ Replacement If a replacement for an existing device, is the existing device analog or digital? ☐ Analog ☐ Digital How many ***insert specific device*** will be required for this application? ____________ What plant system(s) is the application a part of? Are there any interfaces of the device with other plant systems? Describe the specific application. Will the device be used to increase the functionality of a current application? If so, how?
2.c.	**APPLICATION C**: Is the intended use a new application or a replacement of an existing device? ☐ New Application ☐ Replacement If a replacement for an existing device, is the existing device analog or digital? ☐ Analog ☐ Digital How many ***insert specific device*** will be required for this application? ____________ What plant system(s) is the application a part of? Are there any interfaces of the device with other plant systems? Describe the specific application. Will the device be used to increase the functionality of a current application? If so, how?

3. For the application with the highest safety significance and/or economic risk, please provide the following information:

What are the safety functions of the system in which the ***insert specific device*** would be installed?

What are the specific safety functions of the ***insert specific device*** within that system?

What would be the impact on plant safety if the ***insert specific device*** were to fail to perform its function(s)?

Are there backup means for performing the safety function(s)?

☐ Yes (if Yes, please describe)
☐ No

Can you think of other failures or failure modes or potential undesired/unintended behaviors of the ***insert specific device*** that would have safety significance (e.g., functions/behaviors that could impact safety)?

☐ Yes (if Yes, please describe)
☐ No

3. (continued)

What functions (if any) does the ***insert specific device*** perform that could impact plant operation or equipment protection?

What would be the impact on plant operation, availability, or equipment protection/health if the ***insert specific device*** were to fail to perform its function(s)?

Are there backup means for performing the ***insert specific device*** functions related to plant operation or equipment protection?

☐ Yes (if Yes, please describe)
☐ No

Can you think of other failures or failure modes or any unintended functions of the ***insert specific device*** that could have economic risk (e.g., that could impact plant operation, plant availability, equipment protection/health)?

☐ Yes (if Yes, please describe)
☐ No

II. Physical Requirements

*(**Note**: If more than one application is being considered, specify the range of requirements or options needed – e.g., option to accept either 125VDC or 120VAC, range of I/O options needed, etc.)*

1. Describe the intended installation, any space constraints, and any unique installation requirements (e.g., must use existing cables)?

   ☐ Size/weight limitations? (please describe)

   ☐ Mounting requirements? (please describe)

   ☐ Other installation requirements:

2. What is the required/intended power supply for the ***insert specific device***? ______________

   Describe any other power supply requirements (e.g., power supply quality).

3. Describe any input/output requirements for the ***insert specific device*** (number and type of I/O): *(Note – less I/O will simplify EMC testing.)*

   ☐ Analog Inputs
   - ☐ 4-20 ma _______ (how many)
   - ☐ RTD _______
   - ☐ Thermocouple __________ (type – J/K/T)
   - ☐ Other _________

   ☐ Analog Outputs
   - ☐ 4-20 ma _______ (how many)
   - ☐ Other _________

   ☐ Digital Outputs
   - ☐ Electromechanical relay _______
   - ☐ Solid state relay ______________

   ☐ Digital Inputs ______________ (how many/voltage)

   Describe any requirements on input impedance, output contact rating, etc.

   Describe how the I/O will be used (e.g., digital inputs for switching control algorithms, digital outputs for alarm annunciation, etc.)

4. Describe any required external communication capabilities.

   ☐ RS-232

   ☐ Modbus

   ☐ Ethernet

   ☐ Others _______________

   Describe how these communication capabilities will be used.

5. Are there any applicable mechanical requirements (e.g., pressure rating, materials of construction, etc.). Please Describe:

III. Performance Requirements

1. Describe the **BASIC** functional requirements for the device (e.g., for single loop controllers: read analog input and remote setpoint, perform PID control algorithm for analog output, digital output for alarm conditions). These should specify the minimum (must-have) functionality required for the device.

2. Check the appropriate box to indicate any desired additional features or options. For each box checked, provide additional information to describe the desired functionality.

   ☐ Input processing (e.g., input signal filtering, etc.)

   ☐ Output signal requirements (output slew rates, output high/low limits, etc.)

   ☐ HMI functionality (additional faceplate functions, configurability, etc.) Describe the desired front panel human machine interface and device display requirements such as setpoint adjustment, information display, and any requirements on type of display (bargraph, numeric/digital, etc.).

   ☐ Test and diagnostic capabilities (on-line and off-line)

   ☐ Adjustability of configurable parameters (e.g., range of adjustment of setpoints, filter time constants, is hysteresis configurable, etc.)

   ☐ Others

   Please describe the desired functionality.

3. Check the appropriate box to indicate any desired performance requirements. For each box checked, provide additional information to describe the desired performance.

- ☐ Input/output accuracy, drift, temperature stability
- ☐ Input/output range
- ☐ Time response requirements for the various functions of the device, from input to output (these may place requirements on internal characteristics such as input sampling rate, scan time, output update rate, etc.)
- ☐ Others

Please describe the desired performance requirements.

4. Environmental Requirements

Seismic: Plant peak response spectra: __________ Is the SQURTS response spectra OK for your plant? ☐ Yes ☐ No

Temperature/Humidity/Radiation: Do you expect to use the ***insert specific device*** in a mild environment only?
☐ Yes
☐ No

If used in harsh environments is required, specify requirements:

EMI: Does your plant specify EMI emissions/susceptibility testing per:
- ☐ EPRI TR 102323-R1
- ☐ EPRI TR 102323-R2
- ☐ Regulatory Guide 1.180

Is the EMI environment at the intended application location(s) known?

5. Behavior under abnormal/faulted conditions: Check the applicable boxes. For each box checked, specify those conditions for which there is a specific, required behavior, and specify any others for which there is a desired behavior or response but it is not a firm requirement:

- ☐ Loss and restoration of power
- ☐ Loss of one or more signal inputs
- ☐ Input signal over/under range
- ☐ Allowable output signal interruption time (e.g., in response to transient surge)
- ☐ Allowable temporary accuracy shift due to EMI
- ☐ Does the device need a required failsafe state (must fail low, or fail to a programmable output level)?

Please describe any required response to abnormal/faulted conditions:

EPRI

IV. Specific Digital Devices
1. Are than any specific vendors/devices that you desire to use? Please specify the vendor and/or model, if known. Please indicate why this vendor/device is desirable, e.g., known operating history or other information on quality of product, good vendor support, device capabilities, etc.
2. Do you have any previous operating history with this device in non-safety applications? If so, please describe (e.g., application, performance, known issues, vendor support, etc.).
3. Are there any devices or vendors that you will not use? Please indicate why.

V. General Comments
Please use this section to provide any additional information that does not relate to a specific question in this survey that you feel is relevant to the qualification of the **insert specific device***.*

B
DIGITAL OVER-CURRENT TRIP DEVICE SURVEY

The following three pages are excerpted from the survey sent to both the EPRI Component Qualification User Group and to the EPRI NMAC Breaker User Group.

Component Qualification User Group
Digital Over-Current Trip Device Survey

Name:_____________________________ Utility/Plant:______________________________

Contact Info:________________________ Breaker User Group:________________________

In 2003, the EPRI Component Qualification User Group identified **digital over-current trip devices for low voltage circuit breakers** as a candidate component for nuclear qualification. The purpose of this survey is to capitalize on EPRI's user groups and obtain additional information from as many utilities as possible. Your responses to this survey will help define the nuclear industry demand for digital over-current trip devices and identify candidate vendors.

Please complete this survey and email or fax your response no later than **May 16, 2003**, to:

Jim Thomas
MPR Associates, Inc.
(MPR is assisting EPRI with this effort)
Phone: (864) 962-0128
Fax: (864) 962-0638
E-mail: jthomas@mpr.com

Your response is appreciated and will be invaluable to our work in selecting a component(s) to qualify.

EPRI

Component Qualification User Group
Digital Over-Current Trip Device Survey

1. Do you have a need to replace existing analog trip devices with a **digital over-current trip device for use with low-voltage circuit breakers**? (to upgrade obsolete equipment or resolve equipment performance issues)

   ☐ Yes ☐ No

2. Identify model/vendor of existing low-voltage circuit breaker(s) and existing trip device(s) that is under consideration for replacement.

   Circuit Breaker ___________________________

   Trip Device ___________________________

3. Describe the specific application(s) and/or specifications for the low-voltage circuit breaker of interest. Which buses/loads does it supply?

4. What are the specific safety functions of the breaker control device under consideration?

5. What other features/functions (diagnostics, power metering/monitoring, communications, etc.) would you desire from a digital over-current trip device?

Component Qualification User Group
Digital Over-Current Trip Device Survey

6. How many devices would you foresee using in your plant(s)? ____________

   Over what time period would the devices be purchased? _____________

   When would the first order be placed? ___________

7. Are there any specific vendors/devices that you desire to use or are considering? Please specify the vendor and/or model, if known. Please indicate why this vendor/device is desirable, e.g., known operating history or other information on quality of product, good vendor support, device capabilities, etc.

8. If you have a identified a specific vendor/device of interest, do you have any previous operating history with this device in non-safety applications? If so, please describe (e.g., application, performance, known issues, vendor support, etc.)

9. Are there any devices or vendors that you will not use? Please identify these and indicate why.

C

DIGITAL VALVE POSITIONER REQUIREMENTS AND SCREENING QUESTIONNAIRE

Generic Requirements for a Digital Valve Positioner

General

- Compatible replacement for existing analog I/P transducers / valve positioners
- Digital device should improve operation and maintenance by providing remote operation, calibration and diagnostic capabilities, improved reliability, improved drift, and less air consumption

I/O Specifications

- Input: 4-20 mA, 10-50 mA, or 1-5 volt, 2 wire (power derived from the input current or voltage)
- Output: 3-15 psig or 6-30 psig
- Failure Alarm: 125 VDC rated contact, and/or "wireless" alarm
- Digital Communication: HART®, Foundation Fieldbus, Ethernet, or RS-485

Operational Features

- Testing and diagnostic features desired, with remote operation, calibration, and troubleshooting using digital communication capabilities
- Ability to access device configuration parameters on-line
- Input/output pressure display desired, as well as current input display
- Field reversible inputs/outputs (modular replacement is an acceptable alternative)
- Programmable PID function is desirable
- On-line health check
- Off-line configuration by hand-held configurator
- Split range control capability
- Device failsafe state should be selectable (programmable), either high or low depending on specific application

- Loss of power or input signal, device should go to its safe position (either full flow or no flow, depending on programmed value)
- Low/high out of range input, output should go to corresponding min/max value
- Allowable output signal interruption time (if not programmable) should be < 5 seconds

Performance Specifications

- Accuracy: < ±0.5% output span
- Linearity: <±0.5% output span
- Drift: <±0.25% over 18 months
- Temperature effect: <±0.5% over 50°F ambient temperature change
- Response Time: Unspecified, but should be similar to analog device
- Steady state air consumption: < 18 scfh@20 psig regulated air input, < 25 scfh@35 psig regulated air input

Environmental Capabilities

- Temperature: 0-130°F
- Humidity: 0-100% RH
- Seismic: SQURTS response spectra curve:
  - 1.0 Hz – 0.42 g's
  - 4.5 Hz – 14.00 g's
  - 16.0 Hz – 14.00 g's
  - 33.0 Hz – 6.13 g's
  - Any accuracy shift during seismic event should be limited to ±5%, and following a seismic event <2%.
- Radiation: 3 x 10^3 R
- EMI: Regulatory Guide 1.180. Allowable temporary accuracy shift due to EMI should be <±10% output span

Digital Valve Positioner Screening Questions

Device Architecture Questions

- Is the device software programmed in PROM or is it a masked program device?
- Number and type of microprocessors
- Device internal architecture complexity – operating system, multitasking, memory allocation, self-diagnostics
- Internal device communications
- Estimate of amount/size of software code
- Are there any known failure modes for the device? What is the device response to abnormal/faulted conditions?

Questions to Assess Dependability

- Is the vendor certified to any quality standards (e.g., ISO)?
- Does the vendor have a written quality assurance program? Was it used for this device? Is there a separate quality assurance organization within the company?
- What industry standards does the vendor follow in software development and quality assurance?
- What software verification and validation methods are used?
- When was the software/firmware used in this product originally developed? How much is new versus legacy code?
- What software development information is available for review?
- What mechanism does the vendor provide for error reporting?
- What approach does the vendor use for software configuration management and change control? What standards does the vendor conform to?
- What is the vendor's corrective action program?
- Describe the process from error report receipt through correction through shipment to the customer.

Operating History Questions

- What is the current version of device hardware, firmware, software?
- How many devices of the current version have been shipped? How long has it been shipping? How many have been recalled?
- What is the device release history? How many of each release of the device are in the field?

- How often is the firmware/software updated? What criteria are used to determine when to perform an update?
- How many (if any) outstanding, uncorrected software errors exist at this time?
- Describe the metrics used for product trends.
- Does the vendor intend to continue producing/supporting this device for the foreseeable future?

Qualification Testing Questions

- What testing has the vendor done to verify published performance specifications, device functionality, response to abnormal events? Are any of these test reports available for review?
- What testing has the vendor done to verify published environmental specifications (e.g., temperature, relative humidity, etc.)? Are any of these test reports available for review?
- EMI testing
  - Has the vendor performed EMI emissions or susceptibility testing?
  - Does the device have any EMI certifications (CE mark, European EMC directive, etc.)?
  - Is the vendor willing to provide the EMI test report for EPRI review as part of the qualification program?
  - What I/O configurations were tested?
  - What test equipment was used to document device performance? Would this test equipment be available to support additional EMI qualification testing performed as part of the generic qualification, if necessary?
  - What were the acceptance criteria for the test? Allowable accuracy shift? Signal interruption time?
  - Does the vendor provide standard EMI filtering available for purchase with the device?
- Will the device survive a 14g earthquake per the SQURTS response spectra? Will it function during the earthquake? After the earthquake?
- Would the vendor support/participate in additional functional & challenge testing necessary to support the qualification effort? Does the vendor have any special test equipment that could be used for this effort?
- Describe testing done during new product development. What tests are done on each unit during routine manufacturing?

General Questions to Assess Vendor Interest/Participation in Generic Qualification

- Will the vendor allow access to proprietary information with appropriate nondisclosure agreements in place?
- Will the vendor support a commercial grade survey and Critical Digital Review?
- Has a commercial grade survey ever been performed on the vendor by NUPIC or by a utility? Has the vendor had any significant interactions with any nuclear utility, especially for safety related applications? Which utility?
- Will the vendor support a Critical Digital Review?
  - Willingness to make hardware/software designers available – specifically those who designed, implemented and currently maintain the device.
  - If selected by EPRI for generic qualification, willingness of the vendor to provide documentation (e.g., software verification and validation plans, configuration management plans, software test reports, etc.) to reviewers in advance of an on-site review.
  - Will the vendor allow access to source code for reviews or walkthroughs?
- Will the vendor provide a list of product users to contact for an Operating History survey, if EPRI formally selects their device for generic qualification?
- Is the vendor willing to consider freezing the software/firmware to support a nuclear model, if determined to be necessary from the CDR process?
- Will the vendor agree in concept to provide error notification to EPRI or a 3rd party dedicator?
- Does the vendor have an active 10 CFR 50 Appendix B quality assurance program?
- Is the vendor interested in offering the subject component to nuclear plants as a 1E device and maintaining the qualification / commercial grade dedication documentation accordingly?
- Is the vendor willing to take on any responsibility in the qualification process (e.g., support additional activities for nuclear sales, support additional qualification testing)?
- What is the vendor's overall interest in the program?

The Electric Power Research Institute (EPRI)

The Electric Power Research Institute (EPRI), with major locations in Palo Alto, CA, and Charlotte, NC, was established in 1973 as an independent, non-profit center for public interest energy and environmental research. EPRI brings together member organizations, the Institute's scientists and engineers, and other leading experts to work collaboratively on solutions to the challenges of electric power. These solutions span nearly every area of power generation, delivery, and use, including health, safety, and environment. EPRI's members represent over 90% of the electricity generated in the United States. International participation represents over 10% of EPRI's total R&D program.

Program: 1009659

Nuclear Power

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