NATIONAL INSTRUMENTS

Medical Device Industry

Vendor Qualification of NI Software and Hardware Products

July, 2012

INFORMATION ONLY

The information provided herein is provided for informational purposes only.

Contents

Introduction

Customers use National Instruments hardware and software instrumentation products in a wide variety of applications across many industries, including as a sub-component of products in regulated markets, such as the medical device industry.

The USA FDA Quality System Regulation 21 CFR 820.50 Purchasing Controls requires medical device manufacturers to evaluate third-party suppliers of sub-components for their ability to meet certain requirements, including quality requirements. When medical device manufacturers use third-party components such as NI hardware or software in their devices, the manufacturers are responsible for ensuring the ultimate safety and effectiveness of the medical device in which the third-party components are used. Similar supplier control requirements are mandated in countries that apply ISO13485 guidelines.

Medical device manufacturers ask that their suppliers provide information to assist them in meeting FDA requirements, to communicate product issues and changes, and to perform quality assurance and configuration management for the products.

NI published information in this document that medical device manufacturers may find helpful when working to qualify NI as a supplier for inclusion in compliance-related vendor qualification files and for use in premarket submissions to the FDA or other regulatory agency.

In this document, NI summarizes and identifies information and services to assist medical device manufacturers in the following efforts:

- Evaluate and document NI and its products for the validation process, including quality criteria
- Use NI products in a safe and effective manner during medical device design and test
- Satisfy regulatory requirements for information in premarket submissions for off-the-shelf software and hardware components from NI

Corporate and Products Overview

About NI

NI is the leading vendor of computer-based measurement, control, and test devices and the pioneer of software-based instrumentation or virtual instruments. Founded in 1976 by several research engineers, NI began as a self-funded company and was privately held by founders and employees until 1995. It is now a billion dollar public company with more than 6,000 employees globally who work in direct operations in more than 40 countries. NI invests approximately 16 percent of revenue in R&D. Please visit investor.ni.com for additional details on NI financial history and standing, including annual reports, 10k filings, and corporate governance, information on the NI management team; its board of directors; and ethics, antitrust, conflicts of interest and various compliance programs.

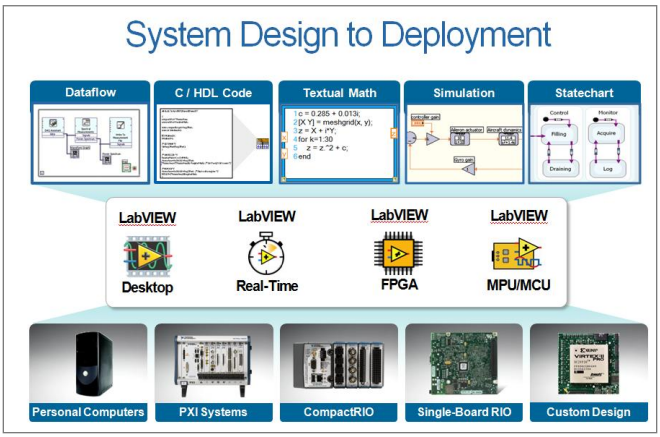
NI equips engineers and scientists with tools that accelerate productivity, innovation, and discovery. NI's graphical system design approach to engineering provides an integrated software and hardware platform that speeds the development of any system needing measurement and control. The company's long-term vision and focus on improving society through its technology supports the success of its four key stakeholders: customers, employees, suppliers, and shareholders.

NI Product History

In its first decade as a company, NI provided commercial off-the-shelf (COTS) interface boards for the IEEE-488 bus standard (more commonly known as General Purpose Interface Bus or GPIB). Customers used these boards to control benchtop and rack-mount engineering and scientific instruments. In the late 1980s, NI entered its second decade by releasing its flagship graphical application development software, NI LabVIEW, and shipped its first plug-in data acquisition (DAQ) boards. With LabVIEW and DAQ, NI made virtual instrumentation possible. Scientists and engineers could use desktop computers with commercial off-the-shelf (COTS) NI DAQ hardware with LabVIEW software to create a variety of cost-effective and highly flexible instruments.

Throughout the 90s, NI released major new versions of LabVIEW and innovative new technologies for machine vision, motion control, and real-time software and hardware, while also releasing additional GPIB and DAQ software and hardware. NI expanded its platform to add products for the new modular instrumentation standard PXI (PCI eXtensions for Instrumentation), which launched a focus on measurement and automation applications and solutions.

In the 2000's, while continuing to advance technology on its current product platforms, NI began its strategic commitment to modular RF-signal range instrumentation products. It also gave customers access to embedded instrumentation technology through field-programmable gate arrays (FPGAs) on NI hardware, and made it easier for non-experts to use through FPGA software tools in LabVIEW. In the mid-2000's, NI launched two lines of more rugged instrumentation systems, NI CompactRIO and NI CompactDAQ.



Today, NI firmly believes its graphical system design approach delivers the hardware and software platforms that equip and inspire its customers to innovate from system design through deployment in areas such as real-time measurements, embedded monitoring and control, hardware-in-the-loop (HIL) testing, and software defined radio.

NI Products in the Medical Device Industry

At least two opposing pressures drive medical device development – Producing safe, high-quality devices is a primary concern, but reduced development time is also critical to establishing early positions in a competitive market. By tightly integrating hardware, software, validation, and reporting tools, the NI graphical system design platform provides the best solution for rapidly developing testing or deploying complex medical devices. Visit ni.com/medical for more information.

Manufacturing and Service Capabilities

NI has manufacturing and major service centers in Austin, Texas US and Debrecen, Hungary. It has built a strong infrastructure in eastern Asia to support its growing base of customers whose contract manufacturers produce product there. NI offers services at its Penang, Malaysia Service Center and will have its third high-volume manufacturing center in Penang.

Refer to page 8 and visit ni.com/environment to learn about NI's environmental policies regarding manufacturing operations. You can find additional information at ni.com/company/corporate-responsibility. Click here to find service locations.

Engineering Resources and Employee Development

The NI business model is to invest 16 percent of annual revenue in R&D. NI has more than 1900 development staff working in global R&D Excellence Centers located in the following areas:

- US
  - Austin, Texas; Colorado Springs, Colorado; Mequon, Wisconsin; and Berkeley, Campbell, El Segundo, Mountain View, San Jose, and Santa Rosa, California
- Canada (Toronto)
- India (Bangalore)
- Asia
  - China (Shanghai) and Malaysia (Penang)
- Europe
  - Denmark (Copenhagen), Germany (Aachen) and Romania (Cluj-Napoca)

NI has experienced teams of software and hardware developers who are responsible for product development. Positions held by key development engineering staff include NI Fellows and Chief, Principal, and Senior Architects – a number of these key employees have worked at NI for more than 20 years.

NI invests to ensure a stimulating work and learning environment. For 13 consecutive years (1999 to 2011), NI has been named among the 100 Best Companies to Work for in America according to FORTUNE magazine. All major NI business organizations, including NI R&D, have dedicated training and development personnel responsible for new hire and continuous education.

NI Quality Focus and Commitment

Quality management applies not only to medical applications, but to any NI-based system used for test and design. In the medical device industry, common guidelines include International Organization for Standardization (ISO) 9001 and ISO13485.

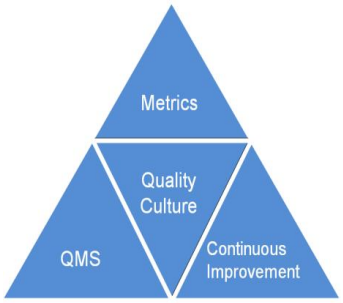
NI is an ISO 9001-certified company. It uses a Quality Management System (QMS) framework to define, communicate, measure, and improve all key company processes to deliver high-quality, reliable products to NI customers. The NI ISO 9001 Quality Management System Certification ensures that NI has processes in place to deliver quality products, services, and support to its customers. The scope of this certification includes marketing, design, development, production, sales, and support.

Through the NI QMS, NI defines, communicates, measures, and improves its processes so that it can achieve its Mission for Success.

Quality Certifications	Locations
ISO 9001:2008	Austin, Texas, USA
ISO 14001:2004	Debrecen, Hungary

NI currently uses the Kaizen framework for continuous improvement, and is institutionalizing lean enterprise concepts and practices.

NI top-level quality metrics include the following:



- Customer Loyalty and Satisfaction
- Product Return Rate
- System Quality Rate (virtual systems)
- Manufacturing Failure Rate
- Supplier Performance Scores
- Measurement Performance – Recalibration
- Software Quality Grades
- System On-Time Delivery
- Return Materials Authorization (RMA) Turn Time
- New Product Introduction (NPI) Reflection; Warranty, Yields

NI has a well-defined NPI process to support its quality initiatives. The NPI process governs taking an NI product from concept to delivery. The NI NPI process specifies all the required steps followed in research, design, development, quality assurance, marketing, manufacturing, sales, and support. NI formally tracks this process in an online Oracle-based system. NI stores documents and source code in revision control systems (such as Perforce and Agile) and uses databases for all testing and issues tracking. Please refer to the following sections on the NI engineering processes for software and hardware product development.

Employee Training on the NPI Process

To ensure that all employees understand the NPI process, a detailed Engineering Process document specifies how NI software engineers research, design, develop, and maintain products. All engineers and project managers receive training on the Engineering Process, which spans the product life cycle phases identified in the NPI process and includes such information as an explanation of each task in the NPI process; a list of required attendees and topics for each NPI meeting; information on how to complete a project plan; and templates for concept proposals, project plans, feature specifications, and review forms.

NI Product Certification and Standards Descriptions

All standard NI products are Underwriters Laboratories (UL) and *Conformité Européenne* or European Conformity (CE) certified, thereby ensuring user safety in accordance with these designations. NI products intended for sale and use in worldwide markets comply with the applicable international requirements for product safety, electromagnetic compatibility (EMC), RoHS, quality, and for use in hazardous locations. Each NI product label will carry the applicable marks for verification of certification. For more details, visit ni.com/certification.

Calibration Accredited to ISO/IEC 17025:2005 and ANSI/NCSL Z540-1-1994


The American Association for Laboratory Accreditation

Accredited Laboratory

NATIONAL INSTRUMENTS
CALIBRATION SERVICES AUSTIN
Austin, TX

Calibration

ISO/IEC 17025:2005 accredited calibration services are critical to manufacturers seeking to maintain compliance with various regulations. ISO 17025 provides the most highly recognized global standard for calibration.

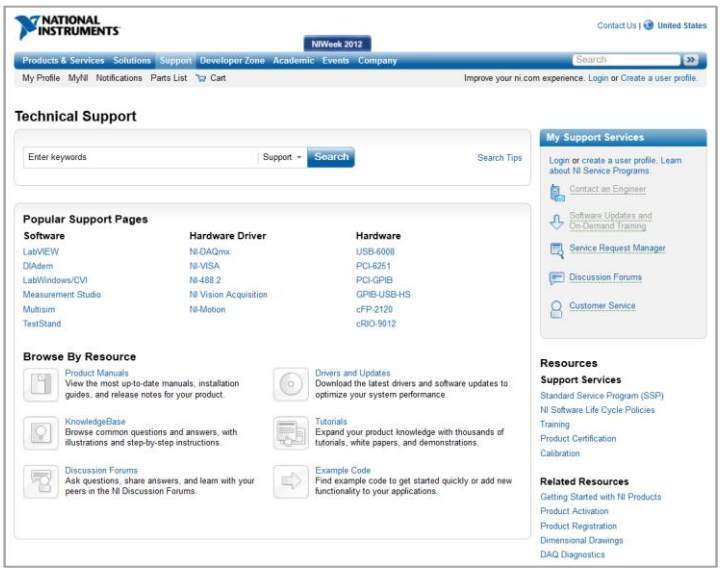
The American Association for Laboratory Accreditation (A2LA) has accredited NI Calibration Services Austin to one of the highest international calibration standards in the industry, ISO/IEC 17025:2005 (General Requirements for the Competence of Testing and Calibration Laboratories). NI Calibration

Services Austin also meets the requirements of ANSI/NCSL Z540-1-1994 and additional program requirements in the field of calibration. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated 8 January 2009).

In addition, NI Certified Calibration Centers located throughout the world can meet local needs and provide the same levels of service. This service includes full calculated measurement uncertainty and the logo of the local accrediting body so that the customer can be confident that the service was performed in accordance with the applicable standard.

Technical Support and Issue Escalation Process

NI has a worldwide technical support organization of applications engineers (AEs) in more than 40 global offices. NI AEs provide first-level technical support online through an award-winning support 24/7 website, and by phone or email for products covered under warranty or a services or support program. In addition, NI engineers with advanced skills, knowledge, and hands-on experience are available for developing projects that require deeper expertise in hardware architecture and software development best practices, and/or knowledge in a specific technical domain, type of application, and/or area of industry.



NI Developer Zone and Technical Community

At ni.com/devzone, NI customers have easy access to information, including tutorials and other publications, example programs, and webcasts and videos. NI customers have also worked with NI to establish an active online community at ni.com/community. Access discussion forums, code exchange, professional groups, and blogs such as Embedded Insights of the Week and submit new product ideas and product feature enhancement suggestions to NI.

Traceability and Accessibility

NI stores AE support reference content in a database called the KnowledgeBase, which customers can access for assistance 24/7.

When a customer requests email or phone support, NI has defined processes globally for receiving, assigning, and monitoring the requests. Each request is logged, given a tracking number, and assigned a response priority.

Customers can log on to the online NI support communication system, Service Request Manager, to

- View the status and summary of service requests (submitted April 1, 2009 or later), including RMA
- Request a hardware repair or calibration
- Get assistance with product activation
- Search web resources and post a question to a worldwide community of experts on the NI discussion forums

Those customers with an active service agreement or support membership can also perform the following tasks using the NI online automated Service Request Manager:

- Contact NI engineers for technical support via phone or e-mail
- View service request notes and e-mail correspondence from NI engineers
- Escalate a support request

When AEs can't resolve a customer issue with an NI product in a timely manner, they follow a precisely defined escalation process that includes involvement of NI research and development (R&D): product support engineers, development engineers, and managers. Once NI and a customer identify a support issue as critical, various NI executives (including NI vice president of quality) engage in the monitoring and evaluation process. NI AEs actively communicate support issues and their resolutions back to R&D for continuous product improvements in the future.

Post Warranty Support

In addition to the 24/7 NI KnowledgeBase system, NI also offers flexible, fee-based support plans for customers needing assistance outside of the standard warranty or requiring special support services, such as after-hours phone/email support, special regional support, a dedicated toll-free support call in number, or other customized support.

NI Corrective Action Process

NI established the NI Corrective Action Request (CAR) system and process that is managed by its quality engineering team and certain R&D personnel. Through CAR, NI tracks bugs, problems, and quality issues with NI products. NI has a defined process for submitting and evaluating each request, and assigning its priority and resolution schedule.

NI Quality Expectations of Its Suppliers

The relationship between NI and its supply base is based on mutual trust, integrity, and world-class performance. NI has a well-defined selection and evaluation process for its suppliers, particular its hardware component vendors. NI selects suppliers that can meet or exceed the NI Supplier Code of Conduct, adhere to all applicable laws and regulations, and perform well against evaluations concerning quality, supply assurance, total cost, and customer service and support. Review the NI Supplier Handbook for one example of how NI communicates with potential suppliers.

Supplier Responsibility, Environmental Management, and Manufacturing Operations

To meet the company's environmental commitments, NI works with suppliers who are equally invested in being responsible corporate citizens. NI also complies with international standards that regulate environmental management and manufacturing operations.

Supplier Citizenship Requirements

To set citizenship expectations with suppliers, NI requires the following from them:

- **Compliance with the Electronic Industry Citizenship Coalition (EICC) Code of Conduct** for the fair treatment of workers, a healthy and safe work environment, the protection of the environment, and outstanding business ethics. Suppliers sign the NI Supplier Code of Conduct, established in 2008, as an acknowledgement of this commitment.
- **Participation in the NI supplier assessment.** NI sends the assessment to all new suppliers in its global supply base, ensuring they comply with key initiatives such as RoHS, REACH, and the NI Supplier Code of Conduct.
- **Completion of a supplier citizenship survey.** NI uses it as a baseline for evaluating a supplier's current corporate responsibility program. These surveys help evaluate a supplier's sustainability in the areas of energy and climate, material efficiency, natural resources, employee programs, and community involvement.

Environmental Management

ISO 14000 addresses environmental management and provides a framework to help participating organizations create an Environmental Management System.

The 14001 standard applies to those environmental aspects that the organization controls and can influence. NI manufacturing facilities— in Austin, Texas, and Debrecen, Hungary – are certified to ISO 14001.

Quality in Manufacturing Operations

NI follows the International Occupational Health and Safety Management (OHSAS) 18001 standard, which helps companies control occupational health and safety risks. The standard is part of the OHSAS 18000 specification.

Manufacturing Site Environmental Permits and Registrations

Visit ni.com/environment to review the company's environmental policy regarding manufacturing operations.

- US Federal – EPA Waste Registration
- State of Texas
  - Texas Natural Resource Conservation Commission Air Permit Exemption
  - Texas Commission on Environmental Quality, Industrial and Hazardous Waste Registration
- City of Austin
  - City of Austin Wastewater Permit
  - Hazardous Materials Ordinance Permit
- Hungarian Ministry—For information about waste registration, contact Mariann Murguly, 9011 36 52 5240, at NI Hungary.
- Hungarian Regional
  - Air Emissions Permit
  - Wastewater Permit

Visit ni.com/company/suppliers for more details. Additional information may be found at ni.com/corporate-responsibility. Readers may also want to review the NI Environmental Compliance Plan as adopted by NI's Board of Directors.

NI Engineering Development

NI uses its New Product Introduction (NPI) process to take a product from concept to delivery, specifying the required steps that are followed in research, design, development, quality assurance, marketing, manufacturing, sales, and support. The NI QMS framework defines, communicates, and measures all key company processes so NI can deliver high-quality, reliable products to its customers.

The company formally tracks this process in a custom Oracle application. NI stores documents and source code in revision control systems and uses databases for all testing and issues tracking. You can find a complete list of all NI certifications for hardware and software at ni.com/certification. Details about the NI software engineering process for product development are provided below.

The Software Engineering Process for NI Product Development

The introduction of all application software and driver software, as well as new products and upgrades to existing products follows the NI NPI process.

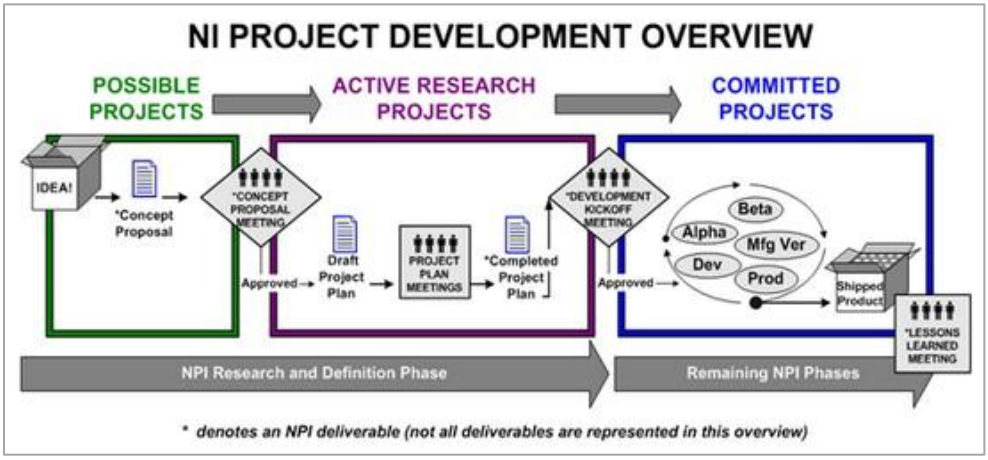


Figure 1 – NI Project Development Overview

Project Status Tracking and Revision Control

NI stores all project documents, including concept proposals, project plans, specifications, design documents, verification and validation (V&V) plans, checklists, software NPI review forms, source code, and tests in a revision control tool or a testing database. NI also stores all source code in a revision control tool.

NI monitors its NPI process in a database using the Oracle Projects application module. This database system includes information that shows the phases, dates, and status of each project. In addition, using a system of electronic checklists and signatures, the database tracks task lists per phase and department.

Project Reviews

The NPI process defines eight specific reviews per project:

- Concept Proposal Review
- Development Plans Review
- Production Planning Review
- Development Phase Exit Review
- Software Prerelease Review
- Software Release Review
- Production Readiness Review
- Lessons Learned Review

Each review must be documented with meeting notes, showing the attendees, action items, and meeting conclusions using a specified review form template.

Critical Roles in the NI Software NPI Development Process

In addition to the software engineer role, several roles are critical to the success of a software feature and project.

Technical Lead—A key role is the technical lead for the feature (or entire project, if the project is small). A senior software developer fills this role and provides guidance and technical oversight for the development of the feature or product. Technical leads are responsible for helping to ensure compatibility, completeness, and correctness of project implementation.

Project Manager (PM)—PMs perform several important functions for the organization. They ensure that the NI R&D processes are being followed, and they act as a focal point for development efforts and communication of status/schedule and risks with all functions (other NI departments and R&D groups) associated with the project.

Product Support Engineer (PSE) —The PSE provides feedback on features, documentation, and possible usability pitfalls that the product might face. The PSE also writes the supportability report and trains AEs on the new product, so they are ready to support customers when NI ships it.

Technical Writer—In order to produce quality documentation, all projects include a technical writer on the engineering team who defines the format of the documentation, as well as develops and edits most of the documentation content.

Phases of the NI Software NPI Process

Research Phase—The research phase is the genesis of a new product. The purpose of this phase is to research a product, validate its feasibility, and determine if the product fits with the NI strategic vision. This phase culminates in a concept proposal, which is reviewed at the end of the phase.

The concept proposal answers questions such as the following:

- What is the product?
- What market will the product serve?
- What risks are involved in developing the product?

At the concept proposal meeting(s), the PM documents meeting minutes using the NPI review forms database and tracks the status of all action items created in this meeting.

Definition Phase—The purpose of the definition phase is to determine the feature set, schedule, and resource plan for the project. The PM incorporates this information into the project plan, which is reviewed for approval at the end of the phase. At a minimum, the project plan includes the following:

- A description and prioritization of features and performance requirements
- The documentation and localization plan, and test, beta, and usability plans
- An initial schedule for each phase of the project

After the project plan is complete, the PM holds a development kickoff meeting to inform the cross-functional team about the plans, deliverables, and milestones for the project. The PM tracks meeting minutes in the NPI database and tracks the status of all action items created at this meeting.

Development Phase—Actual software development occurs during this phase. Developers review and test overall functional feasibility with test cases, and develop test procedure specifications (TPSs). TPSs are procedural descriptions of how to test one or more test cases. See the section "Software Verification and Validation Process" (page 11) for more information. Developers use test cases to verify software execution from a user or system perspective. They execute tests multiple times during the release cycle and execute again (as regression tests) for future releases to ensure that new functionality does not break existing functionality.

Technical Specification and Design Documents—NI uses an iterative approach to software development. Developers describe features in the project plan in a general way. Then, during software development, the PM or the engineers write specifications for each feature.

NI R&D uses specification and design documents to define the feature requirements and the ways it will be implemented. Each major feature listed in the project plan requires a specification. Engineers review and update specification and design documents as needed. They review code based on the policy specified in the project plan. Unit testing is performed by the engineer writing the code.

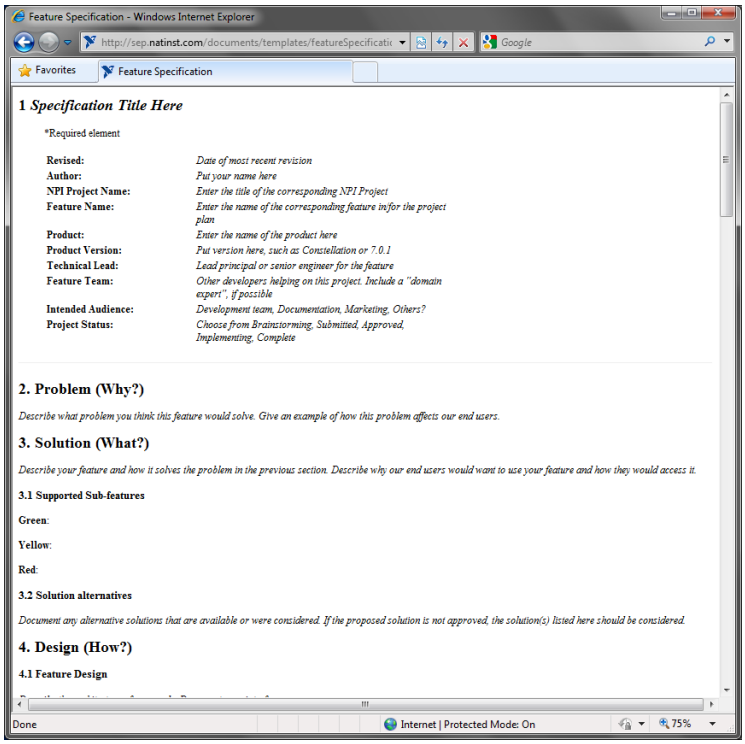


Figure 2 – Template of a Feature Specification

Specification, Design, Implementation, and User Interface Reviews—These reviews are intended to ensure that the design meets the specification and to identify the biggest risk areas.

Additionally, PMs may require a formal or informal code review and a user interface review. During formal code review, several experienced software developers outside the development team (who have reviewed the code ahead of time) give results of their analysis to the developer(s). An informal code review usually involves fewer engineers. During a code review, developers examine and discuss the following items:

- Correctness of logic
- Completeness
- Interaction with other components
- Robustness and error handling
- Readability
- Conformance to coding standards/practices.

Test Design—During this phase, developers create test cases and test design specifications as part of the software design and implementation. See 'Software Verification and Validation Process' below for more information.

Alpha Phase—The alpha phase is critical to attaining a high level of software quality. During this time, the product is tested within the development group, by other internal users, by the cross product integration team, and by AEs. The main focus of the alpha

phase is to execute system tests to ensure a certain level of product completeness and correctness and to fix CARs required before customer use of the released product.

During this phase, the V&V plans and TPSs are created. See "Software Verification and Validation Process" below for more information.

Beta Phase—The purpose of this phase is to ensure shipping quality. For most projects, the beta testing program includes external customers. A test plan is frequently sent to each beta tester with the software. The plan asks the beta tester to exercise certain aspects of the software. At a minimum, NI requests that beta testers run existing applications to find areas of upgrade incompatibility. A web-based beta test database is used to help track and manage the beta program.

Internal testing continues during the beta phase. Additional system performance and usability tests are performed along with "freeform testing"—testing the product by freely developing applications like users do.

During the beta phase, NI tracks various quality metrics, such as the incoming CAR rate and backlog, to understand the maturity level of the software as well as the V&V results, including the number of test days/cycles for the release and the number of test specifications executed per test cycle, along with the test results.

Software Verification and Validation Process

The software V&V process overlaps with the development, alpha, and beta phases.

The PM and engineers create the V&V plan for the project, and review and update it as needed. Based on the V&V plan, the engineers develop system tests, which consist of automated tests and/or hand test procedures. The engineers then execute the tests, and store all discovered problems in the CAR database as individual CARs.

Engineers are responsible for creating test cases, short descriptions of what is to be tested. Typically, features require a large number of test cases. A review of the test cases for a particular feature is done as part of the design review.

NI R&D uses a testing database to track test cases, test design specifications, test procedural specifications, and test results, including when the test was run, the pass/fail status, and who ran it. Engineers log failed tests in the testing database, and create appropriate CARs in the CAR database.

Many products have significant automated regression test suites that verify compatibility and conformance to specifications. Products with significant user interface content rely more on manual tests.

In addition, a cross product integration team develops and executes tests designed to find issues with the integration of many products. If team members detect problems, they file CARs on the offending product. The project manager and lead engineers review the CARs periodically to assess and prioritize them. Engineers retest the code once it has been corrected. The project manager and lead engineers review the test results and test coverage and update the V&V plan as necessary.

The Hardware Engineering Process for NI Product Development

The NI hardware engineering process is similar to the software engineering process for embedded firmware. Physical hardware products also follow a similar defined NPI process which includes the following:

- Concept Proposal Meeting
- Development Kickoff Meeting
- Production Planning Meeting
- Development Phase Exit Review Meeting
- Hardware Prerelease Meeting
- Hardware Release Meeting
- Production Readiness Review Meeting
- Lessons Learned Meeting

Critical Roles in the NI Hardware NPI Development Process

In addition to the hardware designer role, several other roles may be critical to the success of a hardware feature and project.

Mechanical Engineer—The mechanical engineer on the team designs product dimensions, shielding, housing, and component placement on printed circuit board (PCB) designs.

> Packaging Engineer—The packaging engineer determines how an NI product is packaged for shipment. This includes determining how the product is protected during shipment as well as the size of type of packaging used. The packaging engineer is involved early in the design process in case special packaging is required. Packaging engineering is a part of the mechanical engineering department.

Compliance Engineers—The EMC and safety engineers provide guidance and reviews throughout the design cycle and conduct required testing.

Layout Designer—The layout designer is a member of the PCB design services team, and provides a complete PCB solution. Generally, the layout designer plays a larger role in a project once the design is past the schematic stage.

PCB Design/Services—Members of the electronic design automation (EDA) team assist the project team by helping prepare a design for layout and manufacturing.

Technical Writer— To produce quality documentation, all hardware projects include a technical writer on the engineering team who defines the format of the documentation, as well as develops and edits most documentation content.

Metrology Contact—This person is familiar with the Calibration Support Process and provides guidance in creating the Driver Adjustment API and Customer Calibration Procedure Document.

CPI and Usability Engineers—Cross-Product Integration (CPI) testing ensures that new drivers and hardware function correctly in multiple OS/installer scenarios on different platforms. NI tests for compatibility with other NI products and ensures applicable technology standards of hardware components are met. There are four different types of testing services in CPI: System Integration, Hardware Specifications, Goldtree Functional, and Ethernet Testing.

NI Manufacturing Process

The mission of the manufacturing NPI process is to provide NI with an efficient method of procuring materials to support prototype, manufacturing verification, and production runs. The manufacturing NPI process defines the transition of software and hardware products to manufacturing.

Forecasting—The NPI material process depends on accurate forecasting. Forecasting is used to predict future demand for components from suppliers using Material Requirements Planning (MRP). There are two categories of forecast: production and engineering forecast. Production forecast is used for released-sellable products that are maintained by production planning. A production forecast is created at the sellable kit level based on: usage history, sales trends, and direct inputs from the

marketing group, the sales force, and considering the financial targets. The engineering forecast is used to define build for internal use.

Material Planning—An Oracle-based system performs thousands of calculations to provide information to various manufacturing groups based on a combination of forecast and sales orders. MRP tells buyers when to place purchase orders (PO's) for raw materials. It also allows for Electronic Data Feeds to NI suppliers. The MRP process tells planning when to reduce or cut build requests and tells production when to start builds to meet demand. NI MRP is an automated method of managing inventory and product builds. Its main goal is to bring in components and manage build jobs so that raw materials arrive just in time to support the product build.

Manufacturing Design Review—The purpose of the Manufacturing Design Review is to check the design for conformance to the Design for Manufacturing (DFM) guidelines, determine the routing of the product through the floor, discuss plans for testing (fixtures, software, and so on), determine whether the design qualifies for in-circuit testing (ICT), discuss CE mark of the product, discuss new components used in the product, and update forecast dates and quantities.

Manufacturing Verification Runs—For manufacturing to ship a product, it must undergo and pass manufacturing verification. A Manufacturing Verification Run is a check on manufacturing's ability to build, ship, and maintain a product.

Manufacturing Verification Database—The Manufacturing Verification Database is used to keep track of each manufacturing verification and prototype job being prepared and run on the floor.

Manufacturing Verification Scorecard Meeting—After a job has finished on the floor, the manufacturing product engineer calls the Manufacturing Verification Product Readiness Review. Attendees at this meeting can include the component engineer, test engineer, electrical engineer, and engineering technician.

Life Cycle Policies and Processes

NI knows that every application has different requirements for support and longevity and is committed to providing the life cycle support that customers need for their applications. NI product life cycle policies indicate purchase availability, support duration, and migration path. Refer to the Services section on the following page for information on life cycle services NI has available.

Hardware Life Cycle

A variety of factors such as technology evolution, market demand, and component obsolescence dictate the life cycle of any given NI hardware product. NI uses several internal processes to track these factors and manage the life cycle of NI hardware products. All NI hardware products follow the standard life cycle policy described in the following table.

Phase	Phase Definition
Active	A product in the Active phase is currently manufactured and available for sale and support. The duration of the Active phase varies according to product line, and is based on various factors such as technology evolution, component obsolescence, and market requirements.
Mature	A Mature product has advanced well into its life cycle, and may be nearing the end of its production life. In general, when an NI product is in its Mature phase, a newer NI product becomes available that has equal or better features and performance at a comparable or lower price. In its marketing and sales materials, NI typically identifies Mature products as "Not Recommended for New Designs" or "Legacy." The combined Active and Mature lifetimes vary according to product line, but can exceed 10 or more years.
Maintenance	When NI decides to discontinue manufacturing a product, it generally offers customers a one-year, last-time buy period. Some circumstances, such as the sudden loss of a key component due to catastrophic or other unforeseen events, may prevent NI from providing a full year of notice. Products purchased during the last-time buy period include the standard NI one-year warranty. In general, a product stays in the Maintenance phase for at least one year after NI announces its last-time buy date (based on the standard one-year warranty period). However, NI will make reasonable efforts to offer support services beyond this one-year period.
Obsolete	The product is no longer manufactured or available for purchase; NI no longer offers support services for it.

For more comprehensive information, visit ni.com/life-cycle/hardware.

Software Life Cycle

NI application software products have standard life cycle policies that define release frequency and support duration. NI also maintains life cycle policies for individual application software. There are three standard life cycle policy phases for software: current release support, mainstream support, and extended support. Each follows a defined process that covers software service packs/maintenance releases (scheduled updates and fixes), access to paid technical support programs, and products available for purchase. For the LabVIEW policy, visit ni.com/labview/product-lifecycle. To review policies for other NI application software, visit ni.com/life-cycle/software.

Product Changes and Notifications

Changes that trigger a product change notification (PCN) initiated through R&D include changes to form, fit, or function; revision changes, regardless of impact to form, fit or function; and any changes to specifications or software functionality.

Under an NI service agreement, customers can receive advance NI alert notifications when there is any change to the covered product.

Global NI Services

NI provides training and maintenance service solutions to aid with the successful deployment of customer solutions in medical regulated industries. Maintenance services include proactive and reactive preventative and corrective maintenance services that reduce total cost of ownership (TCO) for the solution. In addition, NI can also offer its expertise and experience through various consulting services.

NI Training

To assist customers to develop their users' proficiency with NI software and hardware, NI offers a variety of training courses and delivery methods. NI-certified instructors conduct classes, and can deliver them

regionally at an NI training facility, on-site at a customer location, and on-line through the NI website. For additional flexibility, NI also offers self-paced courses.

Using LabVIEW for Test and Automation in Regulated Markets

To assist customers developing and testing products for regulated environments, NI developed a special course, "Using NI LabVIEW for Test and Automation in Regulated Markets." Through this class, engineers learn to navigate regulatory requirements and business demands when using LabVIEW software for test and automation in regulatory markets, specifically in a regulated industry such as medical device test. During the course, attendees also explore best practices for design validation and manufacturing test using a fictional example of a medical device manufacturing test fixture, maintained throughout the course to illustrate concepts and provide a basis for discussion. By incorporating these efficient and reliable development processes, customers can address business and regulatory risk considerations while ensuring the success of any test and automation project being developed.

Key Course Objectives

- Review published regulatory requirements
- Explore best practices for using standards and application life cycle processes
- Learn the GAMP 5 risk-based approach for developing test applications
- Examine NI tools and techniques to simplify testing and documentation requirements for specific applications

Click here for the detailed course outline. For a detailed course overview, click here and complete the request form.

NI Software Developer Certification—Validate Employee Expertise

NI customers may also have NI certify their engineers and scientists in certain NI software tools. NI uses a standard, industry-accepted method in its certification process, so organizations that invest in NI certification can be sure their employees have the skills needed to perform their jobs efficiently and effectively using NI software. Additionally, engineers certified at higher levels can often provide technical leadership, mentoring, and guidance to less experienced developers.

Maintenance Services

NI provides certain services listed below with its standard one (1) year hardware warranty. NI offers many services on a per-instance or transactional basis and other services through a multi-year subscription program or special maintenance agreement.

- Standard and advanced technical support and maintenance
- Hardware repair services at a module and system level
- Calibration services, including 17025 accredited calibration
- System assurance programs (assembly, configuration, and test for NI systems)

Life Cycle Management Services

While the flexibility of NI modular platforms allows customers to independently manage the life cycle of their application systems, NI also provides the following services to help more efficiently manage NI-based systems throughout the planned life cycle.

- Standard Product Notifications—NI alerts customers about recalls, service reminders, and last-time buy notifications for all registered NI products.
- Product Change Notifications (PCN) —Under an NI hardware service agreement, customers can receive advance NI alert notifications when there is any change to the covered product. Changes

that trigger a PCN include changes to form, fit, or function; revision changes, regardless of impact to form, fit or function; and any changes to specifications or software functionality.

- Product Life Cycle Analysis—NI can provide a regular report on the life cycle status of products and recommended updates, and planning services related to future sustaining engineering.
- System Life Cycle Engineering—For a more thorough evaluation, experienced NI engineers can provide life cycle engineering consultations on a specific application. This can include remote assessment of component wear and tear, software code review for ease of migration, on-site evaluation of system life span, or even co-engineering services for upgrading existing systems. NI can provide in-depth knowledge of a wide range of instrumentation technologies and applications to augment customers 'staff or reduce project timelines.
- Reserved Product Inventory—Once NI has issued a last-time buy notice, NI reserves quantities necessary to meet customer need for the life cycle of the applicable system if the customer enters a maintenance service agreement. NI stores reserved products in a dedicated inventory at a regional NI Service Center.
- Same Model Repair Service—To extend the service of an NI product, NI can assure customers they will receive the same model on returns for repair service. Unlike the transactional repair service, which is subject to the availability of standard product support, this maintenance agreement option provides customers with the same model in return for any product submitted for repair. Under the same model repair service, NI manages the availability of test capability and components, and maintains intellectual property and trained technicians to ensure that customers' system products are repaired or replaced with the same system model. By electing the same model repair option, customers can virtually eliminate the risk of system changes by prolonging the support of the specific NI devices.

For more general information about global services, visit ni.com/services.

NI Alliance Program

The NI Alliance Partner Network is a program of more than 600 companies worldwide that provide complete solutions and high-quality products to the user based on graphical system design. From products to systems to integration to consulting and training services, Alliance Partners are uniquely equipped and skilled to help solve some of the toughest engineering projects. Certain members of the NI Alliance Partner Network are integrators with experience in achieving validation with NI products under medical guidelines. To search for a partner, visit ni.com/alliance/ and click on Find a Partner in left navigation bar.

For Additional Vendor Qualification Assistance

Contact your local NI field sales team by visiting ni.com/global for contact information.

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