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## **1.0 POLICY/PURPOSE**

Santa Barbara Applied Research ensures that its products meet or exceed quality objectives by utilizing a design control process that ensures design safety, reliability, maintainability, and conformance with requirements. The purpose of this work instruction (WI) is to describe the processes followed by the Santa Barbara Applied Research, Inc. (SBAR) operating units to ensure that quality objectives are met in accordance with SBAR's *Design and Development Control Procedure*.

### 2.0 SCOPE

This WI applies to all software design work under the direct control of SBAR.

# 3.0 REFERENCES AND DEFINITIONS

## 3.1 References

ISO 9001: Quality Management Systems-Requirements, Third Edition (2000-12-15)

- ISO 9001 Element 4.2.4, Control of Records
- ISO 9001 Element 7.2.1, Determination of Requirements Related to the Product
- ISO 9001 Element 7.2.2, Review of Requirements Related to the Product
- ISO 9001 Element 7.3, Design and Development

### SBAR Documents

- SBAR *Quality Manual*
- SBAR Contract Review Procedure
- SBAR Design and Development Control Procedure
- SBAR Control of Quality Records Procedure
- SBAR Inspection and Testing Procedure
- SBAR Software Configuration Work Instruction

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### 3.2 Definitions

<u>**Customer</u>:** Recipient of a product or service provided by SBAR. The customer may be, for example, the ultimate consumer, user, beneficiary, or purchaser. The customer can be either external or internal to SBAR.</u>

**Design:** Applies to any process that creates a new process, service, or product or a modification to an existing process, service, or product to accomplish the customer's stated requirements or specifications.

**Design Modification:** A design to update or upgrade an existing system, equipment, software, or component within an existing entity (e.g., software program, Part Task Trainer (PTT), system, system component.).

**Design Repair:** A design to be repaired or fixed based on identified software trouble reports (STRs) or predicted defect or a back-fix of a current installation to an existing entity (e.g.: software program, PTT, system, system component).

<u>New Design</u>: A design for construction of a new entity and/or the installation of a system, equipment, software or component onto a new entity (e.g.: software program, PTT, system, system component).

**New Equipment:** Equipment that is not replacement-in-kind for existing processes or that is being procured for use in new or modified processes.

<u>New Installation Design</u>: A design for the installation of a system, equipment, software or component onto an existing entity (e.g.: software program, PTT, system, system component).

**<u>Product</u>**: Result of activities or processes. A product may include service, hardware, processed materials, software, or a combination thereof. A product can be tangible (e.g., assemblies or processed materials) or intangible (e.g., knowledge or concepts), or a combination thereof.

**<u>Project Manager</u>**: As used in this WI, a senior supervisory individual who is responsible for specific software design effort.

**Service:** Result generated by interaction between the supplier (i.e., SBAR), the customer, and supplier internal activities to meet the customer's needs. Service includes actions taken by SBAR after delivery of the product in accordance with the contract statement of work (SOW).

**Specified Requirements:** Identified standards that detail how conformity is to be achieved in order to produce a quality product or service. Standards include, but are not limited to, the SOW, manufacturers' recommendations, customer written instructions, and technical orders.

**<u>Statement of Work (SOW)</u>**: The document listing the contractual requirements that SBAR and the customer have agreed upon.

**Validation:** Confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use is fulfilled. In design and development, design validation

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occurs after the design has been verified and seeks to determine if the final product or service meets the customer's needs.

**<u>Verification</u>**: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification occurs prior to design incorporation into the product or service being delivered to the customer.

Working Design: Any design in progress prior to final approval.

### 4.0 **RESPONSIBILITIES**

#### 4.1 Software Services Manager

The Software Services Manager is responsible for this WI.

#### 4.2 **Program Manager**

The Program Manager has overall responsibility for design control procedures.

#### 4.3 **Project Manager**

Responsibilities of the Project Manager are as follows.

- Developing design task assignments for approval and submittal by the SBAR contracts or subcontracts administrator.
- If design is required, upon customer approval, initiating a Project Number or Work Order (as applicable), and developing a design SOW detailing the project scope.
- Attending design review meetings and reviewing all meeting minutes.
- Reviewing and approving final design documents submitted by the Project Engineer.
- Supervising all design work, and coordinating the efforts of the preparer, checker, and approver.
- Coordinating approach, research, checks, origination, and layout and obtaining input from other engineers, customer, etc., as required.
- Monitoring the project budget, and notifying the Program Manager in accordance with contract and Federal Acquisition Regulations (FAR) requirements.

### 4.4 **Project Engineer/Leader**

The Project Engineer/Leader, or designee, is responsible for the following (as applicable).

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- Developing and submitting design cost estimates for SOWs issued by the Project Manager.
- Accepting, reviewing, and signing approved design efforts or purchase orders issued through the contracting process.
- Appointing a Project Leader to manage each design project.
- Verifying that all designs are prepared in accordance with this WI.
- Remaining cognizant of work performed in the preparation, check, and approval of designs.
- Reviewing all final design packages prior to submittal to the Project Manager.
- Coordinating and leading design reviews. Coordination shall include notification of all appropriate attendees and transmittal of design documents in accordance with project requirements and personnel availability prior to the scheduled review.
- Keeping and submitting design review minutes.
- Resolving action items resulting from design reviews.

Ensuring that all required documentation is collected and placed in the project file.

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# 5.0 **REQUIREMENTS/PROCEDURES**

#### **Figure 1 – Process Flow for Design Control**





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## 5.1 General

## 5.1.1 SBAR Requirements

Typical policies addressing the design control requirements of SBAR's *Design and Development Control Procedure* and ISO 9001 Element 7.3, Design and Development, include the following:

- The approach to defining requirements ensures that adequate consultation exists between SBAR and the customer to specify the requirements.
- The design is testable so that we can prove that the design meets the requirements.
- The product requirements specifications are subject to documentation control. A backup is retained on computer readable media.
- The requirements specification is subject to configuration management as documentation. SBAR keeps track of the distribution of specification versions (see SBAR Software Configuration Management WI).
- Changes to the product requirements specifications after release are performed under formal change management procedures. Each change is subject to a complete review by the established software configuration board (typically includes developer, customer, and quality assurance personnel). The board establishes the impact of the change before the change is scheduled for inclusion in the next version of the requirements specifications.
- If the product requirements specifications are not acceptable to the customer, then corrective action is initiated.

### 5.1.2 SBAR Requirements

SBAR has a process in place to control and verify the design of products to ensure that the specified requirements are met. SBAR designs are planned, controlled, verified, and validated. Requirements for designs are documented via formal design documents, design reviews are held as appropriate, and design changes are made in accordance with documented procedures.

The requirements of this WI include, but are not limited to:

- Programming or program developments
- Development of PTTs
- Electronic drawings, graphics, video, digitized sound (multimedia materials), and their integration
- Modifications to existing software material.

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## 5.2 Design and Development Planning

The Project Manager or designee identifies the scope of the project design, identifies the qualified support staff to work on the project, and specifies the schedule based on requirements and project budget prior to initiating work, in accordance with the *SBAR Contract Review Procedure*. As applicable to the project, some or all of the following planned activities are executed by the appropriate competent personnel, as designated by the Project Manager.

- Design reviews
- Design verification
- Design validation

Design plans, schedules, and cost estimate documents are created in the applicable format, per customer designation, program software requirements, etc., using the latest SBAR template.

## 5.3 Organizational and Technical Interfaces

The task assignment group typically includes the SBAR project team, the customer quality assurance representatives or the customer Technical Point of Contact (TPOC), and subcontractor design leaders, unless otherwise specified in the project SOW or task requirements.

The Project Leader coordinates project activities with the required support personnel and serves as the point of contact for SBAR on the design project. The Project Leader is responsible for all required design reviews and liaison documentation, such as trip and telecom reports.

### 5.4 Design Input

Design input is usually the requirements specifications of the contract. Other input may be provided or used, e.g., specific product design manuals. All design input is recorded and reviewed for suitability. Reviews of previous designs, where appropriate, form part of the review of design input.

Establishing customer needs (understanding the problem) may require a specific activity (not listed) and one or more of the following activities:

- Face-to-face conversation with customer, E-mail, or call from existing customer or future potential customer telling us about their requirements
- Work with customer to prepare a requirements specification
- Review the specifications, and ensure the specifications are understood and accepted by the customer

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- Determine the criteria to know how and when the specifications are satisfied
- Pass/fail tests criteria and descriptions to know when the job is finished

Where applicable, designs may also use the following inputs:

- Division Guidelines
- Office/site guidelines standards

The design process starts with adequate input; therefore, the established procedures (see Figure 1) are used to review the design input. Agreements on project requirements specifications are established and documented on the SOW before starting the design.

The Project Leader is responsible for ensuring that designs conform to the applicable guidelines, standards, and regulations. Information contained in the design may include, but is not limited to, the following:

- Software/hardware configuration requirements
- Installation conditions/requirements
- Inspection and test requirements
- Shipping requirements

During the creation of the design, the Project Leader periodically reviews the design to ensure that it will be suitable for the intended purpose. The Project Engineer pays close attention to the following items in accordance with SBAR and customer requirements:

- Ease of installation
- Installation compatibility
- Unusual maintenance concerns

After the Project Leader has completed the design documentation, each design is checked and signed by an engineer (peer review), other than the preparer, who has previous experience in performing similar designs in accordance with SBAR and customer requirements.

Changes made to the final design after the approver has signed the design are made in accordance with customer requirements, SBAR standards, or this WI.

### 5.5 Design Output

Software comments, reports, specifications, drawings, sketches, and commercial or benchmarked computer programs are used to document design output. The design output specifies or refers to acceptable criteria for the design. The design review process is used to verify that the design input requirements are met.

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The format and content of the design output is defined. This may include a documentation table of contents or a definition of the computer model to be produced.

- Meet input requirements
- Contain reference data
- Review documentation before release

#### 5.6 Design Review (as required)

The Project Leader leads design reviews with specialized support as required, in accordance with customer and/or SBAR requirements. Table 1 is a sample checklist for documenting the design review/deliverables process. The <u>design review checklist shown in</u> <u>Attachment 1</u> (as applicable) is maintained as a record of review in accordance with SBAR's Control of Quality Records Procedure and ISO 9001, Element 4.2.4.

The intent of the design review is to confirm that the design meets the objectives of the project SOW and conveys information necessary to construct or establish the design. The Project Leader is responsible for having the appropriate support personnel participate in the design review. A design review is performed and documented at completion points required by the customer or in accordance with SBAR standards. Typical design review requirements may include one or more of the following completion points: 30, 60, and/or 90 percent.

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## Table 1. Sample Design Review Deliverables/Critical Events Checklist

CDRL	Title	Start	Due Date	Accepted?	Required	Comments
		Date		Yes or No	Documentation	
4.001	Title of first	Contract	Draft. (antar data		Completed?	Is mosting with TDOC
A001	The of first	Contract,	<b>Draft:</b> (enter date			Is meeting with IPOC
	delivery	DO, or	nere when it is due)			needed to review the
		task start	Final: (enter date			delivery?
		date	here when it is due)			If yes, establish it
						If no, get acceptance
						letter signed
A00N	Title of N		<b>Draft:</b> (enter date			Is meeting with TPOC
	delivery		here when it is due)			needed to review the Nth
			Final: (enter date			delivery?
			here when it is due)			If yes, establish it
						If no, get acceptance
						letter signed
	30%		As required and			Schedule 30%
	Completion		mutually agreed with			Completion review if
	1		TPOC			required by SOW.
	60%		As required and			Schedule 60%
	Completion		mutually agreed with			Completion review if
	1		TPOC			required by SOW.
	90%		As required and			Schedule 90%
	Completion		mutually agreed with			Completion review if
	1		TPOC			required by SOW.
	Other %		As required and			Schedule other %
	Completion		mutually agreed with			Completion review if
	I		TPOC			required by SOW.
A00?	Monthly		First Report Due:			
	Progress		(enter date here when			
	Reports		it is due).			
	*		Subsequent reports			
			due NLT 10 working			
			days after the last day			
			of each calendar			
			month.			

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The design review ensures that the design is safe, reliable, maintainable, and conforms to requirements. The project manager, technical specialist, quality management representative, manager, or customer may, at any time, call for a design review to be conducted outside of the schedule. The design review procedure includes a description of the objectives of the review, identification of the qualifications of the reviewer(s), and mechanisms for recording review results and ensuring that recommendations resulting from the review are implemented. Should another form of design verification be deemed appropriate, then this alternative form is described in the project quality plan. Such verification methods may include carrying out alternative calculations or comparing the design with a similar proven design.

### 5.7 Design Verification

When required and approved by the customer, contracting officer, or designated official, a qualified engineer (assigned by the Project Manager) completes a design verification to ensure that the design output meets design input requirements (if applicable). Design verification is performed via tests, prototypes, demonstrations, or mockups to confirm designs that cannot be readily verified by calculation or for designs that are "non-standard." The type of design verification/validation is determined on a case-by-case basis, taking into account customer expectations and requirements. Design verification and validation activities are documented and included in the project file.

Design output verification is provided through the following or other appropriate methods:

- Comparison with proven design
- Qualification tests
- Review of documents before release

An appropriate customer representative signs off the design to indicate that design verification has been completed.

### 5.8 Design Validation

Design validation (test) specifications are prepared in accordance with the project quality plan or defined processes to meet the acceptance criteria. Acceptance criteria are specified in the product requirements specifications and/or the design output.

Design validation for software is done through testing. SBAR ensures that what is developed conforms to the requirements specification. Internal verification and validation is completed by an individual who was not involved in the design process.

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The validation specifications may be another project deliverable if required by customer and should be reviewed and signed off. The design is validated by completing the following (or other appropriate tasks):

- Ensure that design verification is successful
- Confirm that the final product meets user needs
- Assess the need for multiple validations

When required and approved by the customer, design validation is performed after installation in order to verify that the final design performs as required. Design validation may include testing in accordance with agreed test procedures. To validate designs beyond simple designs, a design validation procedure is written. Results of the validation are documented and maintained in accordance with *SBAR's Control of Quality Records Procedure* and ISO 9001, Element 4.2.4.

### 5.9 Design Changes

Design changes are documented, reviewed, and approved by qualified personnel prior to implementation. The customer is notified of all pending design changes, and provided with electronic and paper versions of all completed paper copy drawings. All engineering/design changes are documented in accordance with acceptable international, national, SBAR, or customer-specified procedures, as applicable. Records of design changes are maintained in accordance with *SBAR's Control of Quality Records Procedure* and ISO 9001, Element 4.2.4.

Changes to the design, programming, and user documentation or design validation specifications after release are performed under formal change management processes. The changes are subject to a review of the impact of the change on other work before being scheduled for inclusion in the next version of the design. Changes are reviewed and approved by the authority that approved the original design, programming, and user documentation or design validation specification, unless agreed otherwise.

When applicable, controlled change procedures include, but are not limited to:

- Identification
- Documentation
- Review
- Approval

**5.10** When a trouble report database is used to track software errors that are discovered while testing, priority 1-2 (5 tier scale) errors must be corrected prior to delivering the product to the customer. If less than 100% of these errors are corrected prior to delivery, this constitutes a "defective" product. A defective product must be presented to the customer with an explanation of the defect, at which point the customer may choose to either accept the product as is, or reject

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if. In either case, the Program Manager (or designee) must record and track the event by initiating a nonconformance process action report.

## 5.11 Transmittal and Control of Final Design Packages

Upon completion of the final design package, the appropriate Project Manager transmits copies of all applicable materials and specifications to the customer. The Project Manager, or appropriate official, signs a letter of transmittal that identifies the contents of the design package. This signature indicates that all appropriate reviews have been conducted. Copies of all final design packages are retained in accordance with *SBAR's Control of Quality Records Procedure* and ISO 9001, Element 4.2.4.

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#### Attachment 1. Design Review Checklist

This checklist is completed for each design project.

Maintain this record, along with the remainder of the design package, in accordance with the Quality Records Program
Contract Name:
Contract Number:

**Design Name/Description:** 

FLEMENT		]	Г	
	ELEWIEINI	YES	NO	N/A
1.	DESIGN AND DEVELOPMENT PLANNING			
<b>1a.</b>	Has a Project Engineer been assigned? If so, list name:			
1b.	Has a Project Leader been assigned? If so, list name:			
1c.	Are properly trained personnel assigned to this project?			
1d.	Are there sufficient resources (e.g., equipment, material) to complete design?			
1e.	Does the design involve existing software?			
1f.	Does design include future expansion possibilities?			
1g.	Does design include installation requirements?			
1h.	Does design include maintenance and/or future upgrades?			
1i.	Does design include operational requirements?			
2.	ORGANIZATIONAL AND TECHNICAL INTERFACES			
2a.	Are meetings with customers recorded, distributed, and filed?			
26	Are important teleconferences recorded and are those minutes distributed to all			
20.	interested parties to ensure there are no misunderstandings?			
2c.	Is there a record of all correspondence (both paper and electronic) with the above?			
2d.	When appropriate, is project correspondence shared with those needing the information?			
3.	Design Input			
<b>3</b> a.	Has the Customer clearly defined design requirements?			
	Are there other design requirements that need to be included in the design? If Yes,			
	list:			
3b.	(NOTE: Include Customer requirements that the Customer may have			
	inadvertently failed to identify.)			
3c.	Does the design include maintenance and future upgrades?			
	Does the design input include handling requirements? If Yes, list:			
3d.		ŀ		
		-		

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FI FMFNT		IMPACT		
		YES	NO	N/A
3.e	Does the design input take into consideration the results of any contract review activities? If Yes, list:	-		
4	DESIGN OUTPUT			
4a.	Is the design output documented and expressed in terms that can be <b>verified</b> and <b>validated</b> against the design input requirements?			
4b.	Does the design output contain or make reference to acceptance criteria? If so, list:	-		
4c.	Does the design output identify those characteristics of the design crucial to the proper functioning of the product? If so, list:	-		
4d.	OPE: Match against paragraph 3, Design input.)         Does the design output meet design input requirements? List who checked the design output against the design input.         Name:			
4e.	Are design output documents reviewed before release? If Yes, list who reviewed the documents: Name:Initials:			
5.	DESIGN REVIEW			
5a.	Are formal design reviews held and documented at appropriate stages of design? If         Yes, list:         30% Date:       60% Date:         90% Date:       100% Date:         (NOTE: Design reviews are conducted at the interval mandated by the Customer.)			
5b.	Are design reviews documented and recorded? (NOTE: Include attendance roster and meeting minutes.)			

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FIFMENT			IMPACT		
	ELENIENI	YES	NO	N/A	
6.	DESIGN VERIFICATION	ļ			
	Is design verification performed to ensure that the design stage output meets the design stage input requirements at the appropriate stages of design? If Yes, list when verification took place and by whom:				
	Name: Initials:				
	Name: Initials:				
6a.	Name: Initials:				
	Name: Initials:				
	Name: Initials:				
	Are the design verification measures recorded? If Yes, list those measures:				
a					
OD.	(NOTE: Design verification, in addition to conducting design review, may include				
	activities such as 1) performing alternative calculations, 2) comparing the new design with a similar proven design if available 3) undertaking tests (e.g. NDE) and				
	demonstrations, and 4) reviewing the design stage documents before release.)				
7.	DESIGN VALIDATION				
	Is design validation performed to ensure that product (designs) conforms to defined user needs <u>and/or requirements</u> ? If Yes, list when verification took place and by whom:				
	Name: Initials:				
	Name: Initials:				
7a.	Name: Initials:				
	Name: Initials:				
	Name: Initials:				
	Are the design validation measures recorded? If Yes, list those measures:				
71.		-			
/0.		1			

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FIFMENT		IMPACT					
	1		EINI		YES	NO	N/A
	(NOTE: Design validation 1) follows successful design verification, 2) is normally performed under defined operating conditions and on the final product, and 3) may be performed in multiples if there are different intended uses.)						
8.	DESIGN CHANGES						
8a.	Are all design approved by au following? Change #: Change #: Change #: (NOTE: Retai	changes and modifications ithorized personnel prior to Date Reviewed: Date Reviewed: Date Reviewed: n a record of all changes/n	s identified to their imp App App App nodification	, documented, reviewed, and lementation? If Yes, complete the proving Official: proving Official: proving Official:	]		
		DECHIDMENTS MAN	DATED D				
9.	ADDITIONAL NATIONALLY	REQUIRMENTS MAN	DATED B DARDS	Y OUR CUSTOMERS AND/OR			
	Division/Contract Design Control Checklists explain how this requirement is fulfilled.						
		ADDITION	NAL COM	MENTS/REMARKS			
							_
Proje	Project Leader Project Engineer						
(Signature) (Date) (Signature)		(Signature) (Date)					
(Project Leader Name) (Project Engineer N			(Project Engineer Name)				



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Date: 18 June 2004

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