1.0 POLICY/PURPOSE

Santa Barbara Applied Research controls and verifies the design and development of SBAR products and services to ensure that the specified requirements are met. Design and development activities are planned, controlled, verified, and validated; requirements for design and development are documented; design and development reviews are held, as appropriate; and design and development changes are made in accordance with documented procedures. This procedure describes the process used by SBAR to ensure that design and development activities meet customer requirements.

2.0 SCOPE

This procedure applies to all designs performed by SBAR or it's subcontractors in support of SBAR's customers. Examples of design and development work include software, marine, electrical, mechanical, structural, and civil.

3.0 REFERENCES AND DEFINITIONS

3.1 References

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

- ISO 9001 Element 7.3 (Design and Development)

Santa Barbara Applied Research Documentation

- SBAR *Quality Manual*
- SBAR *Control of Quality Records Procedure*

3.2 Definitions

Customer: 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.

Design and Development: A set of processes that transform requirements into specified characteristics (distinguishing features, either inherent or assigned) or into the specification for a product/service, process, or system. (**NOTE:** The terms "design" and "development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development process.)

Design and Development Review: Documented, comprehensive and systematic examination of a design to evaluate its capability to fulfill the requirements for quality, identify problems, if any, and propose the development of solutions.

Engineering/Design: Any process/product incorporating engineering, design, drafting, disciplines as either stand-alone or any combination thereof to accomplish the customer's stated goals.

Modification Design: A design to update or upgrade an existing system, equipment, software or component within an existing entity (e.g., ship, platform, facility, building, etc.).

New Construction Design: 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., ship, platform, facility, building, etc.).

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

New Installation Design: A design for the installation of a system, equipment, software or component onto an existing entity (e.g., ship, platform, facility, building, etc.).

Product: 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.

Project Number/Engineering Work Order: A unique, alphanumeric designator that identifies a specific design tasking.

Repair Design: A design to repair or fix identified or predicted defect, or a back-fix of a current installation to an existing entity (e.g., ship, platform, facility, building, etc.).

Replacement-in-Kind: The use of only those materials and spares that fully meet the written specifications for the service.

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 SOW.

Specified Requirements: Identified standards that detail how conformity is to be achieved in ordered to produce a quality product or service. Standards include, but are not limited to, the SOW, manufacturers' recommendations, national standards such as ASME, ANSI, ABS, customer written instructions, tech orders, etc.

Statement of Work (SOW): The document listing the contractual requirements that SBAR Engineers, Inc., and the customer have agreed upon.

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

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 occurs after the design has been verified and seeks to determine if the final product or service meets the Customers' needs and often involves some form of testing.

Verification: 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. It often involves calculations, performed by someone other than the individual who accomplished the design and development that is being verified.

3.3 List of Acronyms

ABS: American Bureau of Shipping

ASME: American Society of Mechanical Engineers

4.0 RESPONSIBILITIES

4.1 Corporate Quality Manager

The Corporate Quality Manager is responsible for this procedure.

4.2 Operating Unit Senior Manager

The Senior Manager within the respective operating unit, as defined by organization charter, has the responsibility for design and development control and for assignment of individuals to implement this procedure.

4.3 Program Manager/Engineering Manager

The Program Manager/Engineering Manager, or designee, is responsible for:

- Review and approval of all engineering/design cost estimates submitted by the project engineer.
- If engineering/design is required, upon customer approval, initiating a Project Number or Engineering Work Order (as applicable), and developing an Engineering Design SOW detailing the project scope.

4.4 Project Engineer

The Project Engineer, or designee, is responsible for (as applicable):

- Review and approval of final engineering and design documents.
- Development and submittal of Engineering/Design Cost estimates for SOWs issued by the Program Manager/Engineering Manager.
- Accepting, reviewing and signing approved engineering/design/drawing efforts or purchase orders issued by the SBAR contracting office.
- Appointment of a Project Leader to manage each engineering/design project.
- Verifying that all designs are prepared in accordance with this procedure.
- Developing engineering/design task assignments for approval and submittal by the SBAR contracting office.

- Designating the preparer, checker and approver for each design.
- Remaining cognizant of work performed in the preparation, check, and approval of engineering/designs.
- Review of all customer requests for SOW's, determination that engineering design is/is not required and submission of bid (s) in accordance with SBAR procedures, for customer approval.
- Review of all final engineering/design packages prior to turnover to the Program Manager/Engineering Manager.

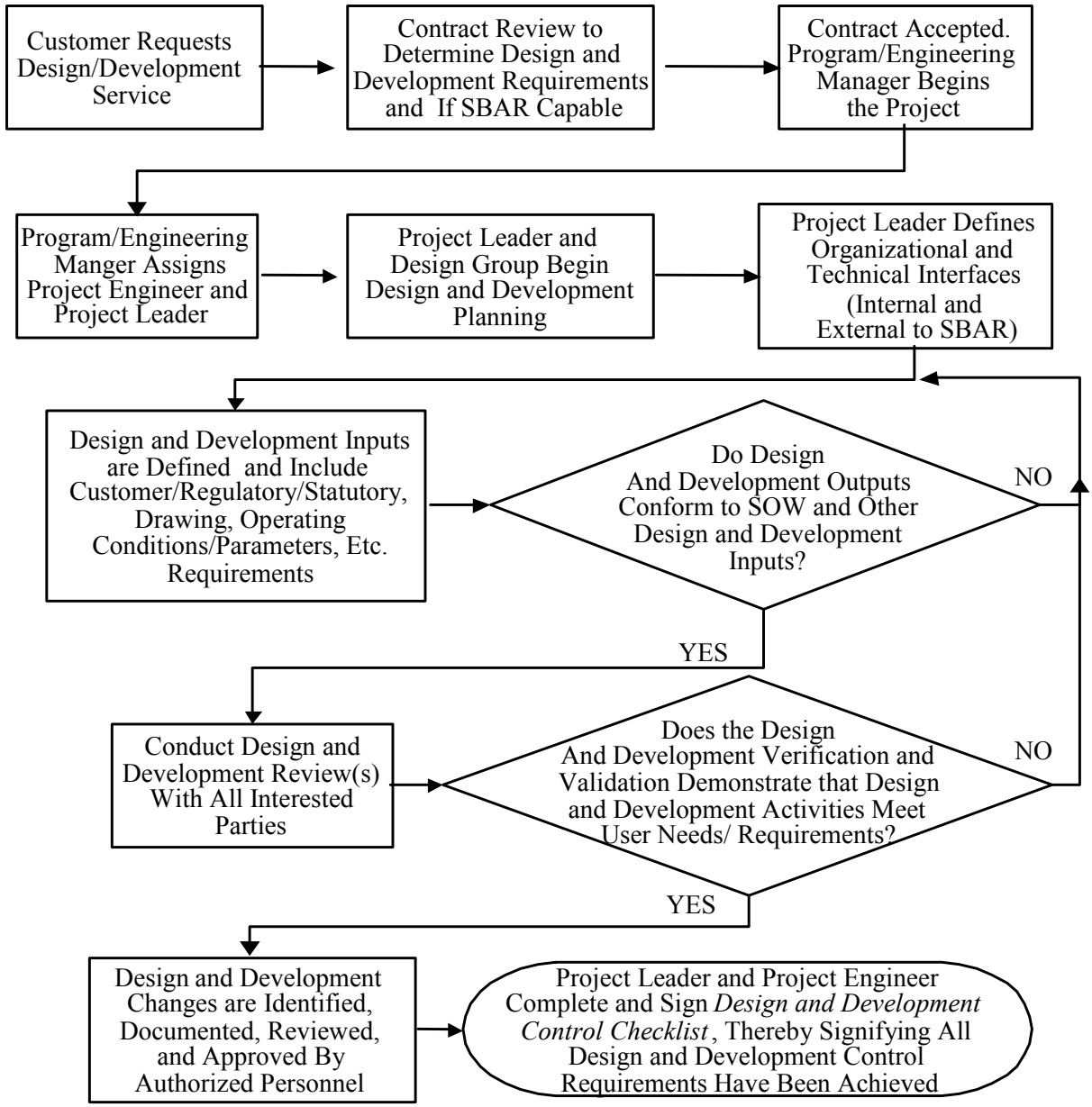
4.5 Project Leader

The Project Leader is responsible for (as applicable):

- Coordinating approach, research, field checks, origination, layout and obtaining input from other engineers, customer, etc., as required.
- Supervision of all drafting and design work, and coordinating the efforts of the preparer, checker and approver.
- Monitoring the project budget, and notifying the Program Manager/Engineering Manager prior to expending 75% of the project budget.
- Coordinating and leading design reviews. Coordination shall include notification of all attendees, and transmittal of engineering/design documents in accordance with project requirements and personnel availability prior to the scheduled review.
- Keeping and submitting engineering/design review minutes.
- Resolving action items resulting from engineering/design reviews.
- Ensuring all required documentation is collected and placed in the project file.

5.0 REQUIREMENTS/PROCEDURES

Figure 1 -- Process Flow for Design and Development Control



5.1 General

The primary means for controlling all designs is the *Design and Development Control Checklist.* If necessary, contracts are authorized to revise this Checklist to fulfill any unique requirements. Further, software design instructions are found in *Design Control Process for Software WI (CP-00-13004-001).*

5.2 ISO 9001 Requirements

Design and Development Control Checklists address the following minimum ISO 9001 standards:

5.2.1 Design and Development Planning

- Do the plans/WIs define the responsibilities and authorities for design and development?
- Do the plans define the design and development stages?
- Are required actions identified for each design/development activity?
- Are qualified personnel assigned to the task in accordance with SBAR *Training Procedure?*
- Have special equipment and resource needs been identified and are they available?
- Are the plans/drawings updated as the design evolves?

5.2.2 Organizational and Technical Interfaces

- Are technical and organizational interfaces that input into the design and development process defined to ensure there is effective communication and the clear assignment of responsibility?
- Is the necessary information documented, transmitted and regularly reviewed?

5.2.3 Design and Development Input

Design and development input requirements are determined and records are maintained. Do these inputs include:

- Functional and performance requirements?
- Applicable statutory and regulatory requirements, relating to the product identified, documented, and reviewed for adequacy?
- Where applicable, information derived from previous similar designs?
- Other requirements essential for design and development?

Finally, incomplete, ambiguous or conflicting requirements are resolved with those parties responsible for imposing the requirements (e.g., contract review activities).

5.2.4 Design and Development Output

Design and development output are documented and expressed in terms that can be verified and validated against design and development input requirements and reviewed/approved prior to release. Do design and development outputs:

- Meet the input requirements for design and development?
- Provide appropriate information for purchasing, production, and servicing?
- Contain or reference product acceptance criteria?
- Does the design output identify those characteristics of the design crucial to the safe and proper functioning of the product (e.g. operating, storage, handling, maintenance and disposal requirements)?

5.2.5 Design and Development Review

Systematic reviews of design and development activities are planned and conducted at appropriate stages of design and development. Do these reviews:

- Evaluate the ability of design and development results to meet the specified requirements?
- Identify any problems and do they propose the necessary actions to correct those problems?
- Do the participants of design and development reviews include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required?
- Are records maintained of such reviews?

5.2.6 Design and Development Verification

- Is design and development verification performed in accordance with planned arrangements (i.e., appropriate stages of design and development) to ensure that the design and development outputs meets the design and development input requirements?
- Are there records of the verification results to include any necessary actions to ensure the success of the product or service?

(**NOTE**: Design and development verification, in addition to conducting design and development reviews, may include activities such as 1) performing alternative calculations, 2) comparing the new design and/or development phase of the product/service with a similar proven product or

service, if available, 3) undertaking tests and demonstrations, and 4) reviewing the design and development stage documents before release.)

5.2.7 Design and Development Validation

- Is design and development validation performed in accordance with planned arrangements to ensure that the resulting product or service is capable of meeting the requirements for the specified application or intended use (where known)?
- Whenever practical, is validation completed prior to the delivery or implementation of the product or service?
- Are there records of the validation results to include any necessary actions to ensure the success of the product or service?

(**NOTE**: Design and development validation 1) follows successful design and development verification, 2) is normally performed under defined operating conditions and on the final product/service, and 3) may be performed in multiples if there are different intended uses.)

5.2.8 Control of Design and Development Changes

Design and development changes are identified and records of those changes are maintained. Additional requirements include:

- Changes are reviewed, verified and validated, as appropriate, and approved prior to implementation.
- Changes include the evaluation of the effect of the changes on constituent parts and products/services already delivered.
- Change review records include, when appropriate, any necessary actions to ensure the success of the product or service.

5.3 Additional Requirements

In addition to the above requirements, the *Design and Development Control Checklist(s)* addresses the following control mechanisms:

- Engineering drawing check procedures.
- Drafting standards.
- Drawing revision configuration control.
- Engineering release of drawings and process.
- Drawing numbers and control.
- Additional requirements mandated by our Customers and/or nationally recognized standards.

5.4 Records and Design and Development Control Checklist

The primary means of recording design and development control activities is a *Design and Development Control Checklist.* For each design and development control effort, a separate Checklist is used to control and record the work effort. Additionally, the following records are also collected and stored in accordance with SBAR *Control of Quality Records*:

- Design/development meeting attendance rosters (e.g., 30%, 60%, 90% design reviews).
- Correspondence with Customers, regulators, etc. concerning designs.
- Customer, regulator, etc. approval of designs.
- Drawings.
- Engineering calculations.
- Other records required by the Customer or nationally recognized standards that document our design and development efforts.

PREPARATION, REVIEW, AND APPROVAL OFFICIALS

Prepared By:

R. W. Stone
Lead Auditor

Reviewed By:

M. T. Schmoll
Director Corporate Programs

Approved By:

Grace Vaswani
President/CEO

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