CMB-S4

QUALITY ASSURANCE PLAN

CMBS4-doc-602-v5

Author(s)	Role/Organization	Date
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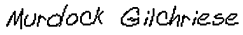
REVISION HISTORY

Version	Revision Date	Description of Changes
v1-4		Early drafts
V5	10/20/2021	Initial release

This document has been officially released by the CMB-S4 project office if:

- A unique DocID number is printed on the bottom-right corner of each document page.
- The document approval page displays a full set of valid e-signatures.
- An e-signature audit trail is appended to this document.

APPROVALS

Name	Project Role	Signature	Date
John Corlett	Project Director		10 / 22 / 2021
Murdock Gilchriese	Deputy Project Director		10 / 22 / 2021
John Carlstrom	NSF Principal Investigator Project Scientist		10 / 29 / 2021
Matthaeus Leitner	DOE Project Manager		10 / 22 / 2021
Jeff Zivick	NSF Project Manager		10 / 27 / 2021
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John Ruhl	Instrument Scientist		10 / 27 / 2021
Julian Borrill	Data Scientist		10 / 22 / 2021

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1 PURPOSE AND SCOPE

This document defines the Quality Assurance Plan (QAP) for the Cosmic Microwave Background - Stage 4 (CMB-S4) Project. This plan provides the framework and processes required to successfully accomplish the CMB-S4 Project goals with the appropriate level of quality to ensure reliability of the experiment performance.

This program follows the Department of Energy (DOE) O 414.1D and integrates quality requirements from LBNL's Quality Assurance Plan LBNL-PUB-3111. The quality program is implemented by quality plans, procedures, and standards which are developed to accommodate specific quality requirements.

The CMB-S4 QAP is applicable to all members of the CMB-S4 collaboration performing work in support of the CMB-S4 Project. All collaborating institutions are expected to comply with the principles, requirements, processes, and practices outlined in this plan.

Additional quality assurance (QA) plans, QA procedures, and additional QA documentation can be developed by collaborators to leverage their existing workflows. This documentation shall be reviewed by the CMB-S4 QA Manager for acceptance to ensure compliance with this QAP.

Specific quality requirements for subcontractors and vendors shall be established or documented in purchasing or contract documents. Additional and specific QA plans, QA procedures, and documentation may be developed for subcontracts. This documentation shall be reviewed by the CMB-S4 QA Manager for acceptance to ensure compliance with this QAP.

This QAP shall be applied through the entire Project lifecycle: design, fabrication, shipment, storage, and installation of the CMB-S4 project.

2 REFERENCES

References used within this document are detailed in the following subsections. Unless otherwise noted, the information contained in this document takes precedence over information contained in referenced materials.

2.1 REFERENCE DOCUMENTS

The following documents contain additional information useful for providing history and context for material contained in this document.

Table 1: Reference Documents

RD#	Document Title	Document No.
RD1	Quality Assurance	DOE Order 414.1D
RD2	DOE Preliminary Project Execution Plan (PPEP)	CMBS4-doc-726
RD3	NSF Project Execution Plan	CMBS4-doc-608
RD4	Quality Assurance Guide for Project Management	DOE G413.3-2
RD5	Subpart A – Quality Assurance Requirements	10 CFR 830
RD6	Quality Guidelines for Research	ANSI/ASQ Z1.13
RD7	QA Program Guide	DOE G 414.1-2B
RD8	Safety Software Guide	DOE G 414.1-4
RD9	Records Management	DOE O 243.1B
RD10	LBNL Quality Assurance Program Description	LBNL-PUB-3111
RD11	Integrated Safety Management Policy	DOE P 450.4A
RD12	Suspect/Counterfeit Items Guide	DOE G 414.1-3
RD13	CMB-S4 Systems Engineering Management Plan	CMBS4-doc-520
RD14	Establishing QA and Safety Grades	CMBS4-doc-728
RD15	Design Review Procedure	CMBS4-doc-673
RD16	Document Control	CMBS4-doc-238
RD17	CMBS4 Template, Acceptance Criteria List	CMBS4-doc-754
RD18	CMBS4 Template, Corrective Action Report	CMBS4-doc-754
RD19	CMBS4 Template, Deviation Request	CMBS4-doc-754
RD20	CMBS4 Template, Engineering Change Note	CMBS4-doc-754
RD21	CMBS4 Template, Nonconformance Report	CMBS4-doc-754
RD22	CMBS4 Template, Work Instruction	CMBS4-doc-754

2.2 ACRONYMS

Table 2: Acronyms

Acronym	Full text
ACS	Acceptance Criteria Strategy
CCB	Change Control Board
CD 1 / 2 / 3	Critical Decision 1 / 2 / 3
CDR	Conceptual Design Review
CMB-S4	Cosmic Microwave Background - Stage 4
DOE	Department of Energy
EH&S, EHS, ES&H, ESH	Environment, Health & Safety
ISM	Integrated Safety Management
L1 / L2 / L3	(WBS) Level 1 / 2 / 3
LBNL	Lawrence Berkeley National Laboratory
MRR	Manufacturing Readiness Review
NCR	Nonconformance Report
NSF	National Science Foundation
P&ID	Piping and Instrumentation Diagram
PDR	Preliminary Design Review
PRR	Procurement Readiness Review
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Plan
QAR	Quality Assurance Representative
RLS	Resource Loaded Schedule
WBS	Work Breakdown Structure

3 QUALITY ASSURANCE POLICY

For this Quality Assurance Plan (QAP) to be fully effective, the CMB-S4 Institutions (lead lab and partner institutions) must understand, accept, and fully implement the quality plan. For this reason, all CMB-S4 personnel are required to be familiar with the requirements, processes and procedures defined within the CMB-S4 Quality Assurance Plan as deemed appropriate for their assigned project responsibilities.

4 QUALITY ASSURANCE PLAN

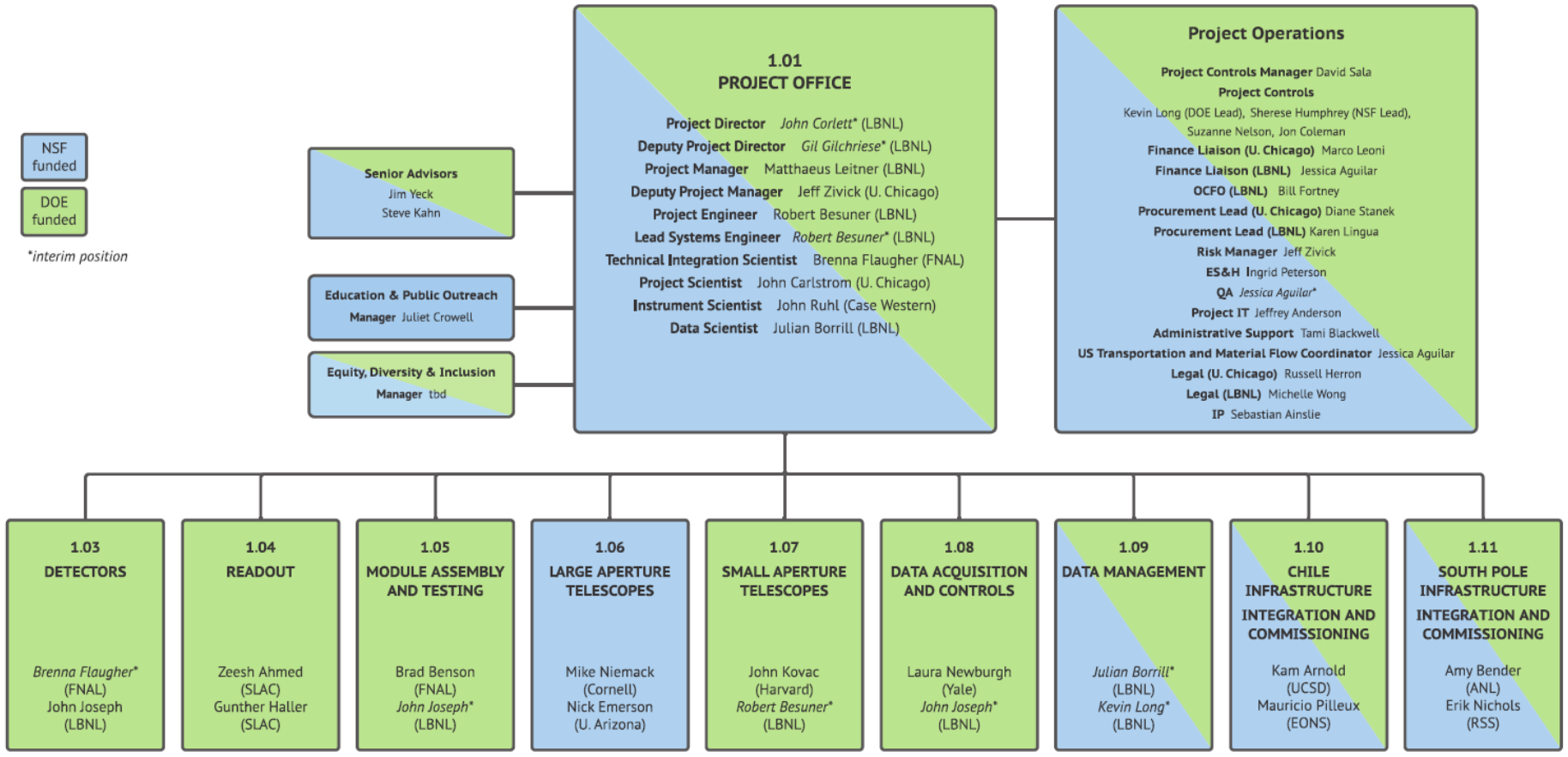
The CMB-S4 Project is managed as described in the NSF Project Execution Plan (NSF-PEP) and DOE Preliminary Project Execution Plan (DOE-PEP). The Quality Assurance Program is approved by the CMB-S4 Change Control Board (CCB). This QAP is reviewed at least annually by the CMB-S4 Project management team, and revised, as necessary, with the approval of the CMB-S4 CCB.

4.1 ORGANIZATIONAL STRUCTURE

The CMB-S4 project organization is described in the PEPs and illustrated in the figure below.

The CMB-S4 Project organizational and management structure is designed to accomplish the project's mission effectively and safely. The CMB-S4 Project utilizes a management and organizational system, supplemented by documented requirements, to establish clear and defined roles, responsibilities, and authorities. The organization chart is periodically reviewed for adequacy, updated, and approved by the Project Director. The CMB-S4 Project Execution Plan describes high level responsibilities and authorities and position descriptions that define the responsibilities and authorities for key positions.

Figure 1: CMB-S4 Integrated Project Office



Date: 09 / 22 / 2021

Approved: John Corlett

4.2 FUNCTIONAL AUTHORITY, LINES OF AUTHORITY & INTERFACES

Responsibility for quality starts with the Project Director and is delegated through the organization. Each Level 2 Control Account Manager (CAM) and Level 2 Science Lead involved in project activities is responsible for the quality of their own work and that of their subordinates. Implementation of Quality Assurance is the daily responsibility of all personnel. It is part of the Level 2 CAM and Level 2 Science Lead duties to ensure that the activities each person is responsible for are compliant with this QAP and all applicable requirements.

The CMB-S4 Project Director, along with the Project Manager, appoint Level 2 Science Leads, who assume responsibility for all aspects, including QA, of these subsystems at Level 2 of the Work Breakdown Structure (WBS) as shown in the PEPs.

4.3 ROLES & RESPONSIBILITIES

The detailed roles and responsibilities of the project management team are listed in the NSF Project Execution Plan and DOE Preliminary Project Execution Plan. The QA responsibilities, in addition to those outlined in the PEPs are below:

4.3.1 PROJECT DIRECTOR

Responsible for project QA.

4.3.2 PROJECT MANAGER

Responsible for project level QA oversight.

4.3.3 PROJECT ENGINEER

Responsible for technical design/performance parameters and technical/QA documentation review.

4.3.4 QA MANAGER

Reports to the Project Manager and is responsible for:

- Developing and maintaining the CMB-S4 Project QAP;
- Assisting the Project Director, Project Manager, Deputy Project Manager and Project Engineer in the Quality Program definition and to coordinate its development and implementation;
- Review and approval of Institutional QAPs and supporting QA documentation;
- Advising project managers in quality matters;
- Providing or coordinating project-specific QA training for CMB-S4 Project members;
- Reviewing completion of QA-related milestones as provided in project schedules;
- Establishing effective working relationships with Institutional QA Representatives of the CMB-S4 and the partner institutions;
- Recommending to the CMB-S4 Project Director that work be stopped and notifying the Level 2 Science Lead based on an investigation that indicates that work is of inadequate quality;
- Carrying out quality audits and assessments of the Quality Assurance Program within the CMB-S4 Project and its suppliers.

4.3.5 LEVEL 2 CAM & LEVEL 2 SCIENCE LEAD

Report to the Project Manager and implement the CMB-S4 Quality Assurance Program within their relevant CMB-S4 project subsystem. Appoint the Manufacturing Engineer and Institutional QA Representative. Responsible for providing released QA documentation for review by the Institutional QA Representative and/or QA Manager such as:

- Design Review documentation
- Released design packages
- Personnel training documentation and records;
- Acceptance Criteria Lists
- Procurement QA Plans
- Shipping Plans

4.3.6 MANUFACTURING ENGINEER

Reports to the Level 2 CAM and Level 2 Science Lead and receives QA guidance from the Institutional QA Representative. The manufacturing engineer has a QA role and supports an institution by evaluating the process of manufacturing, identifying potential improvements, and creating and implementing engineering solutions. The manufacturing engineer duties include:

- Ensuring current and released documentation is utilized by the project staff;
- Controlled monitoring and measurement devices (calibrated tooling) are in use where required;
- Coordinating personnel training and ensuring that only trained personnel are assigned to the appropriate work activities;
- Studying existing manufacturing processes and identifying strengths and weaknesses;
- Identifying potential improvements in product design and assembly line processes;
- Creating protocols to improve optimization of the product line, in technical and budgetary aspects;
- Completing Acceptance Criteria Lists and delivering completed documentation to the Institutional QA Representative;
- Completing Deviation Requests and Nonconformance Reports when these quality issues arise, and delivering completed documentation to the Institutional QA Representative;
- Informing the Institutional QA Representative if any suspect counterfeit items are found;
- Consulting with the Institutional QA Representative for QA guidance.
- Assisting with inventory control

4.3.7 INSTITUTIONAL QA REPRESENTATIVES

Each Level 2 CAM and Level 2 Science Lead needs to ensure that the Institutional QA Representative is identified and receives QA guidance from the QA Manager. Creates and maintains institutional Quality Assurance Plans that adhere to the CMB-S4 QA plan. Works with the Level 2 Science Lead on implementing institutional QA processes.

The QA Representative supports the QA Manager by monitoring the activities during the design and construction stages of the Project to ensure the processes, materials, and systems being procured and used by the Project meet the specified quality requirements and are in conformance with the QA Plan. The QA Manager and the Level 2 CAM will determine the requirements for specific QA staff to participate in designs, design reviews or supervise field activities.

The Institutional QA Representative is also responsible for audits:

- To ensure that released documentation are used during manufacturing;
- To ensure controlled monitoring and measurement devices are within calibration;
- To ensure Acceptance Criteria Lists are complete and the data collected is within allowable tolerances;
- To ensure Deviation Requests and Nonconformance Reports are complete and work with the Manufacturing Engineer and SME to determine the disposition and any additional actions required.

4.3.8 SUBJECT MATTER EXPERT (SME)

Reports to the Level 2 CAM and Level 2 Science Lead and provides technical support for QA activities.

4.3.9 MANUFACTURING ENGINEER

Reports to the Level 2 CAM and Level 2 Science Lead and receives QA guidance and support from the Institutional QA Representative. Creates QA documentation. Oversees production and ensures documentation is complete.

4.3.10 INSTITUTIONAL PROCUREMENT

The procurement person (buyer) or team at the Institution that facilitates purchases. Supports Level 2 CAM and Level 2 Subsystem purchases. Works with requestor on subcontractor QA management.

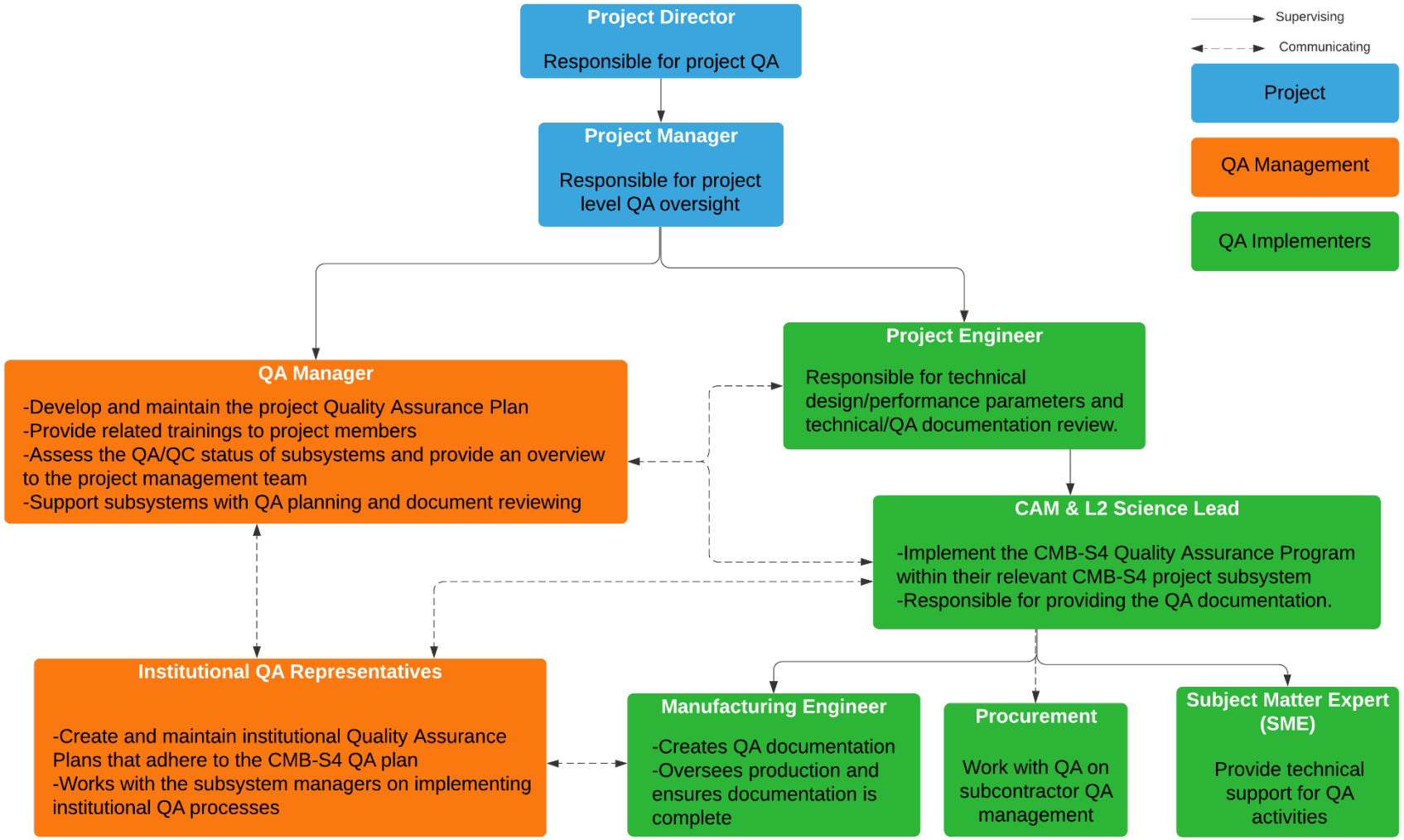


Figure 2: QA Roles and Responsibilities

4.4 QUALITY ASSURANCE COORDINATION

Coordination between the different QA Representatives (QAR) is ensured by the QA Manager through training and the establishment of standard QA processes. The primary purpose of the coordination effort is to assure that equivalent approaches to QA are implemented across the entire project. All QA processes, utilized within partner institution facilities, will be cross-referenced to the QA processes defined within the primary CMB-S4 QAP (this document) to assure compatibility and effectiveness.

QARs will:

- Assure that QA is performed in a manner consistent with the CMB-S4 QA Plan and associated procedures;
- Participate in the design of items and systems, incorporate specific QA requirements into specifications, and develop acceptance strategies for verification and testing;
- Participate in vendor qualification efforts, and monitor compliance throughout the manufacturing process;
- Assure that inspections of items and services, as received or performed, conform to specified requirements, and assure that quality is maintained during delivery;
- Perform periodic assessments to confirm ongoing compliance with the project's QA requirements.

4.5 GRADED APPROACH

The CMB-S4 Project shall implement a graded approach which gives flexibility in the degree of rigor involved when implementing QA requirements. This allows the requirements to be applied appropriately to items and activities dependent on the deliverable's functionality and potential cost, schedule, scope, or safety impacts.

The graded approach is a process for determining that the appropriate level of analysis, control, documentation and necessary actions are commensurate with an item's or activity's potential to:

- Create an environmental, safety, or health hazard,
- Delay project schedule,
- Incur significant monetary cost to the project, or
- Unfavorably impact the programmatic mission of the project.

The risk matrix in Table 3 will be used as a guide for the CMB-S4 project graded approach implementation. Additional information on specific implementations of the graded approach is mentioned elsewhere in the QAP and in supporting documentation found in Table 4. Any interpretation needed for QA requirements or graded approach application of the quality program requirements implementation shall be provided by the QA Manager.

Table 3: Graded Approach Determination Guide for CMB-S4 QA Levels

Risk Level	Impact				
	Scope	**Schedule**	**Environmental**	**Safety**	**Project Cost Exposure**
Level A High Impact	Potential for significant adverse impact to the completion of the CMB-S4 Project or achieving key performance goals. Potential for moderately adverse impact to the CMB-S4 project by affecting one or more WBS L2 subsystems or components.	Potential to delay the project schedule by more than 6 months	Hazard to the safety and health of workers, public and environment including exposures near regulatory limits, minor environmental release outside of building but on site, or major release within building.	Significant impact to the safety of CMB-S4 personnel or is a DOE reportable incident. DOE non-reportable incident	Potential financial loss of greater than $1,000,000.
Level B Moderate Impact	Potential for moderately adverse impact to the CMB-S4 Project by affecting one or more WBS L2 subsystems or components. Potential for minimal impact to the CMB-S4 project task, single L2 WBS subsystem, or component.	Potential to delay the project schedule by 3 to 6 months	Minor hazardous material released within building.	Minor or negligible impact to the safety of CMB-S4 personnel.	Potential financial loss of $250,000 to $1,000,000.
Level C Low Impact	Potential for minimal impact to the CMB-S4 Project, task, single L2 WBS subsystem, or component.	Potential to delay the project schedule by less than 3 months	Minor hazardous material released within building.	Minor or negligible impact to the safety of CMB-S4 personnel.	Potential loss of less than $250,000.

Table 4: Actions for the Determined Quality Grade*

Action & DocDB #	Levels A	Level B	Level C
Establishing QA and Safety Grades CMBS4-doc-728	Requires ES&H & QA review and signature	Requires ES&H & QA review and signature	No signature required
Design Review Procedure CMBS4-doc-673	Design reviews and independent verifications	Design reviews and verifications	Little or no design reviews or validation
Document Control Procedure CMBS4-doc-238	Thorough, released documentation such as: • Technical specifications • CAD models • Drawings/Schematics • Statement of Work • Assembly Instructions • Acceptance Criteria List • Additional special requirements if needed	Adequate and appropriate, released documentation such as: • CAD models • Drawings/Schematics • Statement of Work • Acceptance Criteria List • Additional documents if needed	Minimal, released documentation such as: • CAD models • Drawings/Schematics • Assembly Instructions
Control of Monitoring and Measuring Devices CMBS4-doc-XXXX	Controlled monitoring and measurement	Controlled monitoring and measurement	Generally, not used
Level of Personnel Training	Documented worker qualifications	Knowledgeable personnel	Knowledgeable personnel
Acceptance Criteria List CMBS4-doc-754	Formal verification required by the Institutional QA Representative. Final ACL is uploaded to DocDB.	Verifications performed by the Institutional QA Representative. Final ACL may be stored locally.	Normal receipt inspection only
Deviation Request CMBS4-doc-754	Formal Deviation process required	Consult with QAR to make determination	Generally, not performed
QA Representative Participation	QA representation required	QA representation as needed	QA representative available
Procurement QA Plan	Mandatory QA representative participation. Vendor qualification and surveillance.	Mandatory QA representative participation.	QA representative participation as needed. Little or no vendor verification.
Control of Nonconformance CMBS4-doc-754	Generated by local site, addressed, and closed with LBNL concurrence	Required, generated, addressed, and closed by local CMB-S4 site	Generally, not used

* Note: The DocDB numbers provide actual instructions within the QA Plan.

4.6 TASK FORCE TEAMS

Task force teams may be appointed by the Project Director to work on resolving significant problems or on improving operations. These teams may be composed of persons from several groups. These teams may work on generic problems such as difficulties with the timeliness of procurements, or the lack of coordination of design activities. These groups will be facilitated by a chair appointed by the CMB-S4 Project Director.

4.7 STOP WORK AUTHORITY

Any individual involved in the project that becomes aware of an activity or workmanship issue that they believe to be of inadequate quality, or any conditions or behaviors that are averse to quality or safety, should bring the condition(s) to the attention of their project management team. Individuals should feel free to raise such issues without concern for retaliation, intimidation, recrimination, or discrimination. It is the responsibility of the institution and project management to investigate the condition(s) believed to be of inadequate quality, to communicate the problem to the Project Director and, to ensure appropriate corrective actions are taken based on the condition(s).

Vendors and suppliers are also required to stop work and consult the project when a condition of inadequate material quality is determined within their facilities.

Project management has the authority to stop work of inadequate quality if deemed appropriate.

5 PERSONNEL TRAINING AND QUALIFICATION

The Project Manager requires that all project personnel be trained and have the appropriate experience to ensure that they are capable of performing their assigned work in a safe and efficient manner.

CMB-S4 Level 2 Science Leads are responsible for ensuring that their staff are adequately trained and qualified to perform their assigned work.

Before personnel are allowed to work independently, the Level 2 Science Leads are responsible to ensure personnel have the necessary experience, knowledge, skills, and abilities. Personnel qualifications are based on factors such as:

- Previous experience, education, and training
- Performance demonstrations or tests to verify previously acquired skills
- Completion of training or qualifications programs
- On-the-job training

ES&H training for collaborators and subcontractors that provide skilled persons for short-term work efforts at institutions other than their home institution shall be coordinated through the host institution’s ES&H Representative.

6 QUALITY CONTROL

6.1 QUALITY IMPROVEMENT

It is Project Management's intent that all CMB-S4 Project personnel be continually alerted to the project's QA Program objectives of preventing conditions and situations that may compromise the successful accomplishment of the technical, scientific, ES&H, and QA goals and requirements of the Project.

There should be a continually improving level of quality in meeting these goals and requirements with the participation of everyone in the early identification, documentation, and remedy of problems that might result in excess costs or schedule delays, among other consequences.

Processes to detect and prevent quality problems will be established, including:

- Equipment and electronic parts inspections and verifications
- Software code inspections, verifications, and validations
- Project reviews
- Baseline change reviews
- Work planning
- External assessments

Item characteristics, process implementation, and other quality-related information will be reviewed, and the data analyzed to identify items, services and processes that need improvement.

Project management encourages a "no fault" attitude regarding the identification of problems that compromise either facility safety or reliability. All project personnel and subcontractors are encouraged to identify problems or potential quality improvements and may do so without fear of reprisal or recrimination.

6.2 CONTROL OF NONCONFORMING PRODUCTS

The CMB-S4 Project shall ensure that products and processes that do not conform to product and process requirements are identified and controlled to prevent their unintended use or delivery. Nonconformance reporting (NCR) (CMBS4-doc-754) is a process to document, analyze and disposition physical products that do not meet manufacturing specifications and quality requirements. An Institution can use their own NCR form if it is approved by the QA Manager. Approval is given as long as key information is captured.

In the case of contractors, they shall provide a systematic approach to the identification, segregation, reporting, review, analysis, corrective action, and re-verification of nonconformance issues. This includes effective labeling and segregation of affected parts so that they are not accidently used in the system being delivered. The contractor’s quality plan shall describe the control processes, including identifying the persons or groups responsible for decisions. Complete records are required of any action or decision made regarding the nonconformance and may be requested during audit or review.

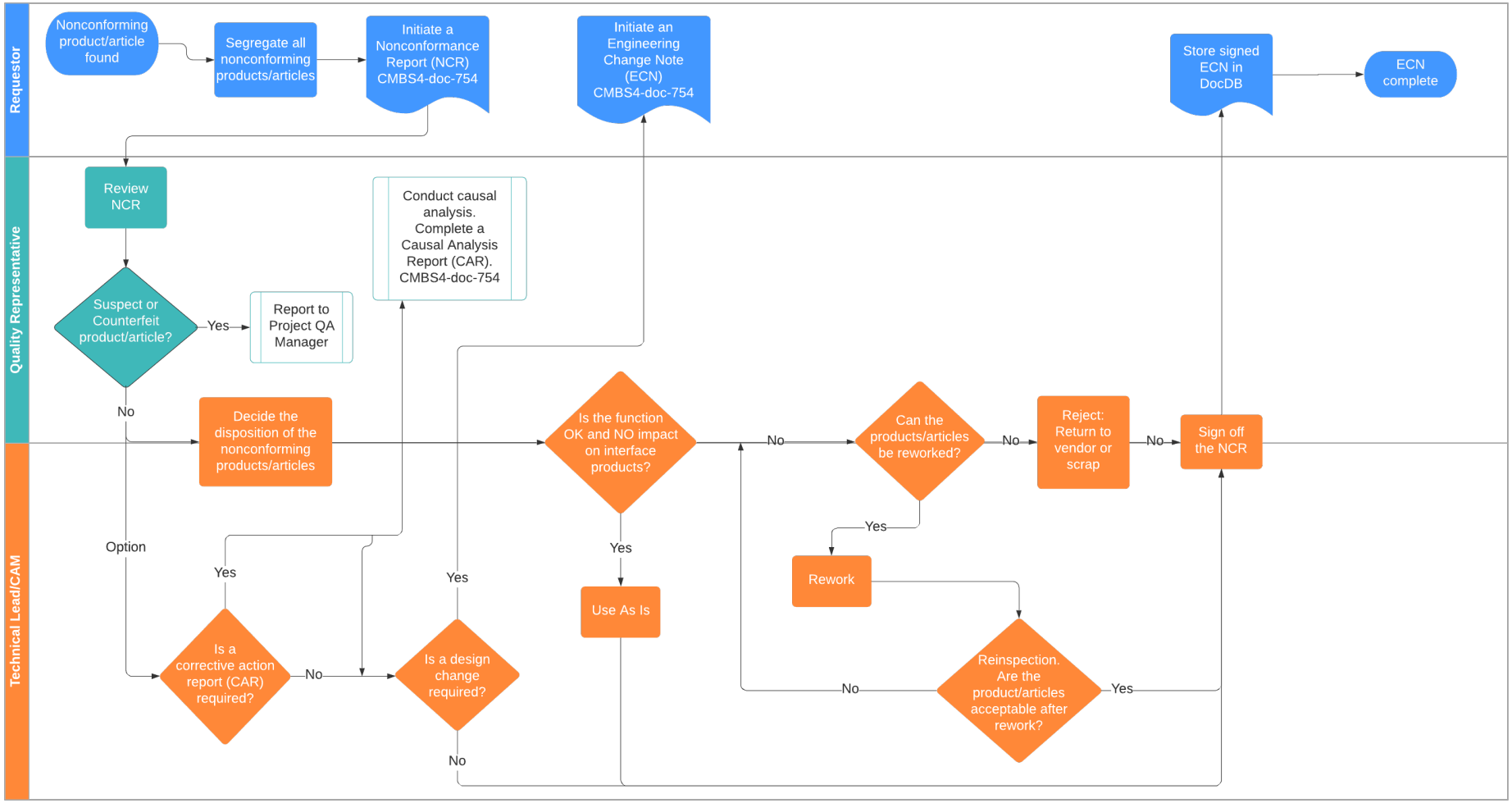
Nonconforming product(s) will be addressed as detailed below:

- Action taken to eliminate a detected nonconformance
- Authorizing and documenting the item’s use under a concession
- Action taken to preclude the intended use or application

Nonconformances will undergo disposition by personnel directly responsible for the safe and satisfactory acceptance of the item or service. For Risk Level A (see Table 3), the NCR may require disposition input from the Project Office, and additional documentation may be implemented.

Level 2 Science Leads shall notify the CMB-S4 project management team if a nonconformance will potentially impact the overall project in any of the categories at the Risk Level A (see Table 3). The image below describes the process for generating, approving, and dispositioning nonconformances.

Figure 3: Nonconformance Process



6.3 CORRECTIVE ACTION

Corrective actions will be taken when identified quality non-conformances exceed predefined acceptability limits, when they deviate from required procedures, when they fail to meet requirements or specifications, especially in the areas that affect safety and reliability.

Corrective actions should identify the affected products so that a decision can be made on whether to accept the product and waive the non-conformance, repair the product, or initiate disposal. The general steps of a corrective action procedure are as follows:

- Review and document the problem;
- Contain or temporarily fix the problem;
- Investigate the cause and determine its root cause;
- Propose an appropriate solution that will prevent the problem from reoccurring;
- Assess the impacts of the proposed solution;
- Implement the solution and report on the actual actions taken;
- Assess the success of the corrective actions and document it; and
- Close the issue when the problem is resolved.

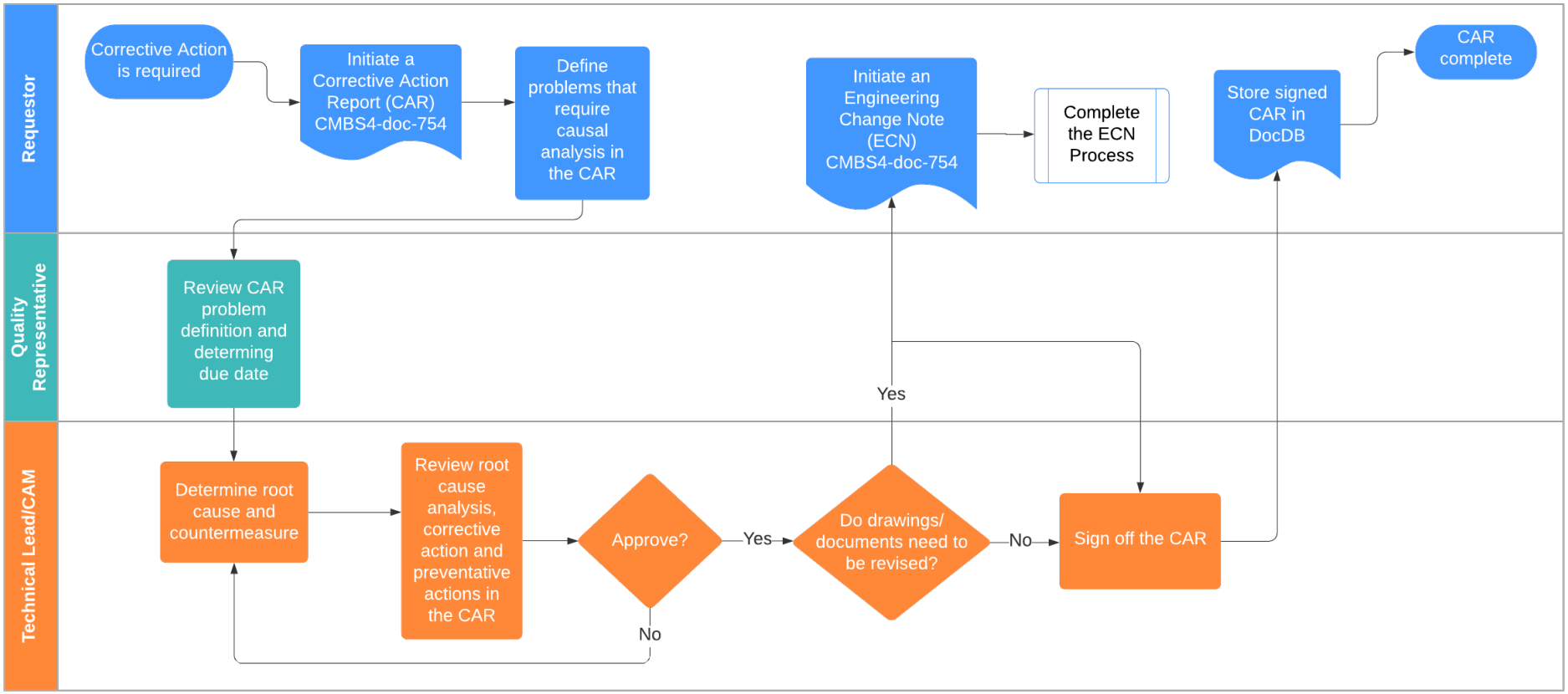
Causes, countermeasures, and recommendations for remedying a nonconformance may be documented via a Corrective Action Report (CAR) (CMBS4-doc-754). Among recommendations from an NCR/CAR could be to (1) keep, rework, or scrap the nonconforming part; and/or (2) an Engineering Change Note (ECN) to make changes to documentation. For Risk Level A (see Table 3), the ECN may require input from the Project Office, and additional documentation may be implemented. An Institution can use their own CAR form if it is approved by the QA Manager. Approval is given as long as key information is captured.

Action will be taken, as appropriate, to rectify and prevent recurrence of significant conditions adverse to quality or environment, safety, and health. The decision to initiate any corrective action will be based upon an evaluation of the seriousness, and the adverse cost and schedule impact of the problem relative to the cost and difficulty of its correction.

The primary responsibility for eliminating or minimizing defective elements and nonconforming articles and for correcting conditions which would initiate these problems rests with the individual group responsible for performing the tasks or producing the articles. The Level 2 Science Lead is responsible for seeing that all appropriate corrective actions are adequate and taken in a timely manner. If the Level 2 Science Lead believes that a correction is not adequate or timely, the problem will be documented and brought to the attention of the Project Director for resolution.

The image below describes the process for generating, reviewing, and approving a CAR.

Figure 4: Corrective Action Reporting Process

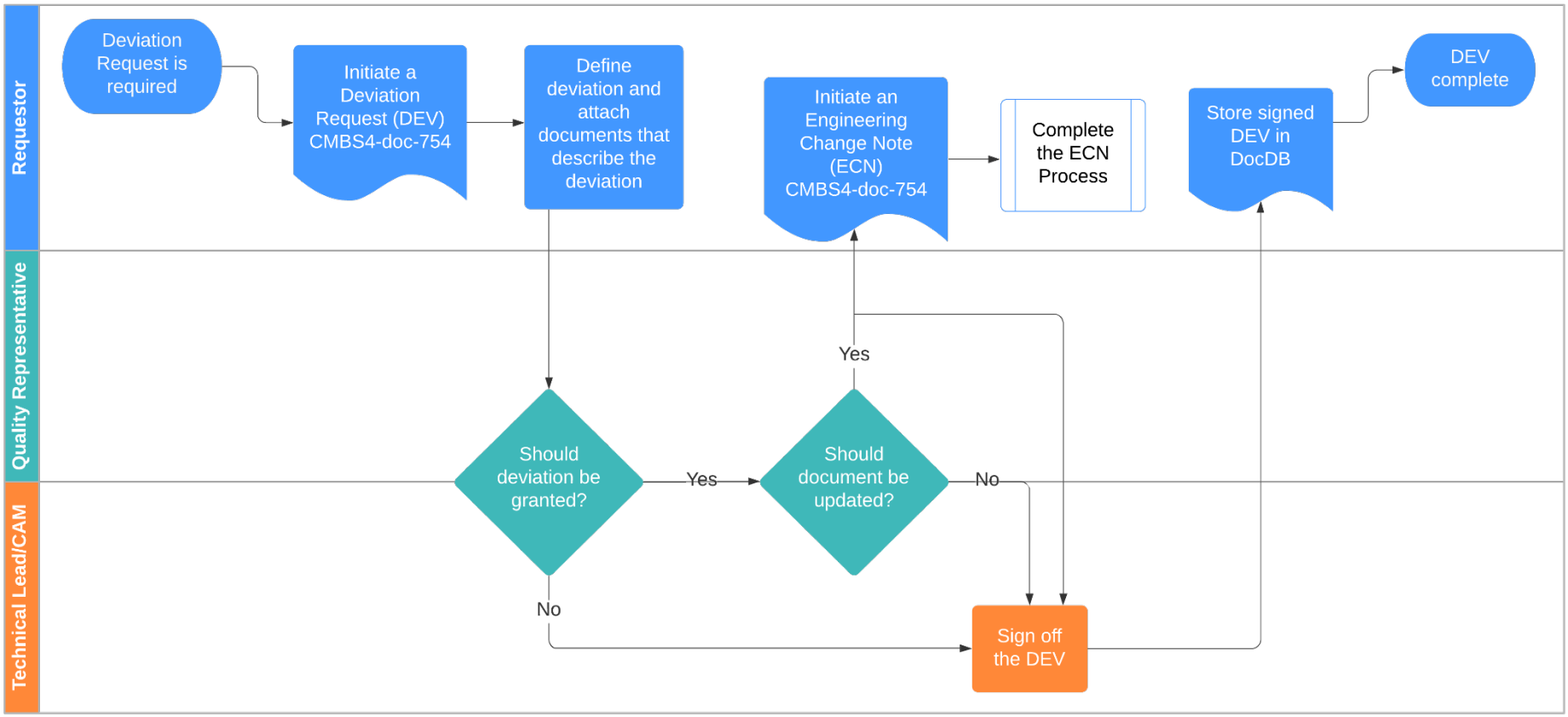


6.4 CONTROL OF DEVIATIONS

The Deviation Request (DEV) (CMBS4-doc-754) is a process used to document, analyze & disposition potential changes to drawings, specifications, drawings, work orders or processes prior to the manufacture of a product. An Institution can use their own DEV form if it is approved by the QA Manager. Approval is given as long as key information is captured. The image below describes the process for generating, approving and disposition of a deviation request.

A formal deviation process shall be established to: document the request; assure that appropriate staff are made aware of the request; record the final decision; and make sure that official records are amended to reflect the change or deviation.

Figure 5: Deviation Request Process



7 CONTROL OF DOCUMENTS & RECORDS

7.1 CONTROL OF DOCUMENTS

The preparation, issuance, and change of CMB-S4 project documents that specify quality requirements or prescribe activities affecting quality such as technical requirements, procedures, and drawings shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be released as defined in the CMB-S4 Configuration Management Plan (CMBS4-doc-238).

Distribution will be accomplished in accordance with the originator's instructions and general needs of other personnel. Although the responsibility for document distribution may be delegated, the responsibility for the positively controlled distribution of such documented information rests with the Level 2 Science Leads or other person responsible for the information or data at issue.

It shall always be the user's responsibility to ensure that they have the current revision of the document before using the information. The user should always check DocDB.

7.2 DOCUMENTATION CATEGORIES

As part of the graded approach, three main categories of documentation have been established for the CMB-S4 project. The category description and change control requirements are listed below.

7.2.1 PROJECT BASELINE ITEMS

These are top level project items used to assess, manage and control technical scope, requirements, schedule and cost. Changes to these items shall follow the Configuration Management Plan (CMBS4-doc-238).

- Resource Loaded Schedule (RLS)
- Technical and Interface Requirements Database (in Jama Connect)

7.2.2 TECHNICAL CONTROLLED DOCUMENTS

Documentation that communicates information needed to produce the project outcome or processes used repetitively during the project. This category includes, for example most documents needed to produce project deliverables; for example, hardware drawings, assembly and test procedures, work instructions, management documents, and acceptance criteria lists. This category of documents is under change control and shall be released as defined in the CMB-S4 Configuration Management Plan (CMBS4-doc-238).

- Mechanical & Electrical Design Drawings & Technical Specifications
- Facility Design Drawings & Specifications
- Technical Design Reports
- Interface Control Documents (in Jama Connect)
- Quality Documents
- Safety Documents

The Level 2 Science Leads will use the graded approach described in this plan to determine which work in their scope requires the preparation of controlled documents. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

7.2.3 INFORMAL DOCUMENTS

Documentation that communicates information or procedures for activities with low significance, consequences, or prototyping activities (as determined by the Level 2 Science Lead) may have fewer formal procedures or instructions. Notes, desk manuals, emails, notebooks, and sketches are acceptable methods for this level of written communication. Document storage for these items may be kept with the technical team at the local institution.

Records are prepared and maintained to provide evidence that activities have been performed or results have been achieved. Level 2 Science Leads are responsible for identifying the records to be preserved.

7.3 CONTROL OF RECORDS

The documented evidence of the quality of completed work will be retained for use during the course of an activity as well as for historical records. Sufficient records will be required and maintained to furnish objective evidence of actions affecting quality. The QA records will be legible and traceable to the phase of the activity, and to the item, process, or operation they apply to. The records shall be retrievable for use in evaluation of acceptability and for verification of compliance with the QA program requirements. Records shall be archived on DocDB, even if generated by hand.

A QA Database search underway and will be implemented between CD-1 and CD-2. The QA Database should consist of:

- E-travelers
- E-QA Checkpoints
- Archive key data
- E-Acceptance Criteria Lists for inter-system handoffs
- Shipping Tracking

8 CHANGE CONTROL

8.1 CHANGE CONTROL REQUIREMENTS

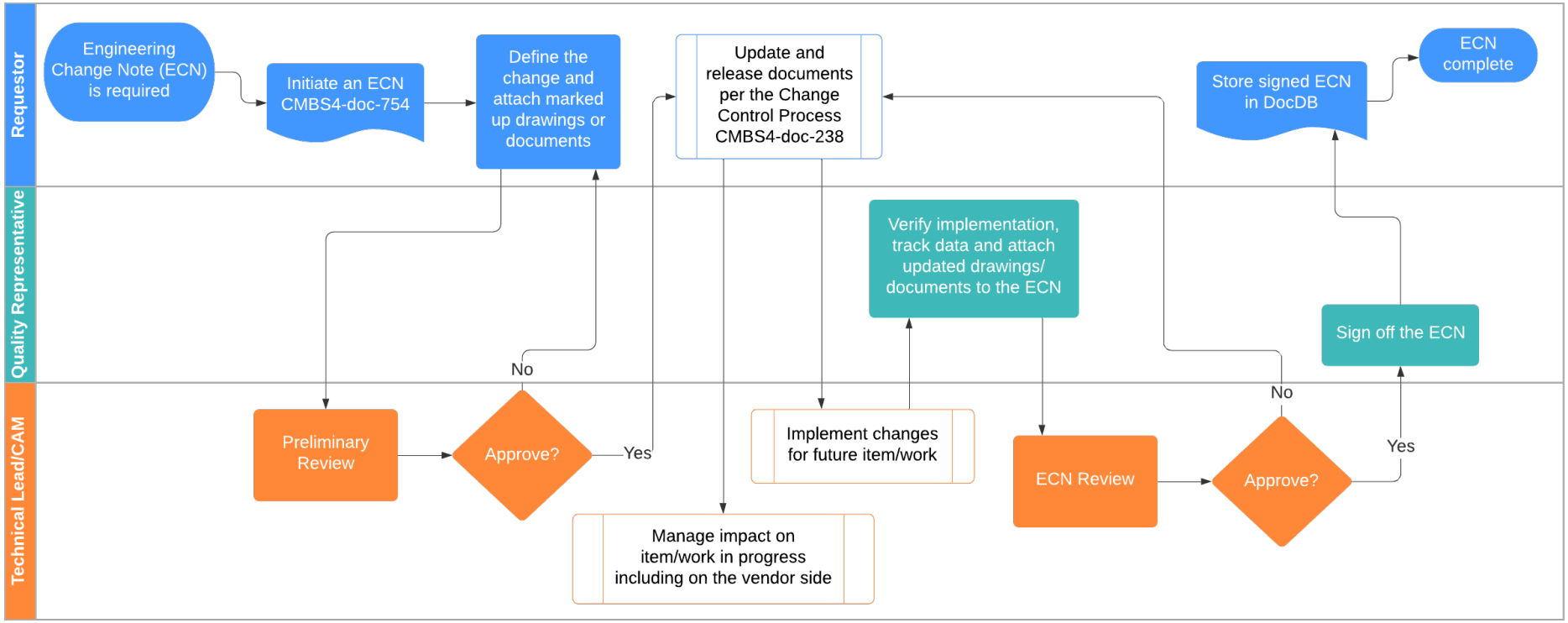
The CMB-S4 Configuration Management Plan (CMBS4-doc-238) describes the method for controlling and maintaining the CMB-S4 Project technical scope, cost and schedule baselines. The Configuration Management Plan requires that:

- Baselines are defined and documented
- Changes to baselines are documented, reviewed, and approved prior to implementation
- A Change Control Board (CCB) and/or clear change approval authorities are identified
- Approved changes are implemented and tracked

8.2 ENGINEERING CHANGE NOTE

Engineering Change Note (ECN) (CMBS4-doc-754) is a document authorizing and recording design changes. ECN documentation contains the justification for changes made to a component or system once the initial design is complete. An Institution can use their own ECN form if it is approved by the QA Manager. Approval is given as long as key information is captured. The image below describes the process for generating, approving, and disposition of an ECN.

Figure 6: Engineering Change Note Process



9 WORK PROCESSES

9.1 WORK PROCESS CONTROL

All CMB-S4 personnel are responsible for the quality of their work, and Level 2 Science Leads are required to identify the resources and support systems to enable staff to do their work. All work will be performed using methods that promote successful completion of tasks, conformance to project requirements, compliance with Environment, Health & Safety (EHS) rules, and compliance with all applicable regulations. Work processes consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls to achieve a result.

In accordance with an Integrated Safety Management Program, Level 2 Science Leads shall assure that the following are clearly identified and conveyed to workers prior to beginning work:

- Requirements for the work and final product
- Acceptance criteria applicable to work and final product
- Hazards associated with the work
- Technical standards applicable to the work and final product
- Safety, administrative, technical, and environmental controls to be employed during the work

Level 2 Science Leads are responsible for assuring that those under their supervision have the skills (including knowledge and understanding of the capabilities of the processes being used), equipment, work process documents, and resources needed to accomplish their work. Workers shall be responsible for the quality of their work and shall be expected to perform their work correctly, in accordance with established instructions and procedures.

Work processes will be managed according to the following criteria:

- Resources – Level 2 Science Leads will ensure that resources and support systems at the various institutions are sufficient to enable their staff to do their work using methods that promote successful completion of tasks, conformance to the project requirements, and compliance with ESH rules.
- Graded Approach – Level 2 Science Leads and institutional QA representatives will use the graded approach described in this plan to determine the appropriate work controls based on the type of work being done.
- EHS – Project Manager will ensure that management of EHS functions and activities is an integral and visible part of the work planning and execution processes, including use of Integrated Safety Management (ISM) guiding principles and worker participation in work planning.
- Training – Level 2 Science Leads and institutional QA representatives will ensure that employees, collaborators, and subcontractors are properly trained in and knowledgeable of the procedures, instructions, drawings, specifications, and other related administrative and technical documents that control their work. Where processes require specially qualified personnel, the performing personnel shall be appropriately trained and certified to the qualified process/procedure before performing those processes.

Work Planning will be managed by the Level 2 Science Leads according to the following criteria:

- Acceptance Planning – Systems or components shall have plans for acceptance based on the creation and completion of verification and test records, using a graded approach.
- Conduct of Work – Work shall be performed safely, in a manner that ensures adequate protection for employees, the public, and the environment, and management shall be accountable for the safe performance of work.
- Item Control and Protection – Items, including consumables, shall be identified and controlled to ensure their proper use and prevent the use of incorrect, unaccepted, or unidentified items.
- Calibration – The necessity for calibration and control is dependent upon the application and criticality of the equipment. Each Level 2 and Level 3 manager shall analyze their work process

measuring and test equipment to determine the appropriate calibration requirements and develop an effective program for the necessary calibration activities. In cases where applicable and relevant industry standards exist, these standards are applied, and the test equipment is used and maintained in accordance with such standards. In cases where the acceptance criteria are based on the particular requirements of the CMB-S4 experiment, industry standards may not exist, and test procedures and equipment must be designed and fabricated specifically for these items.

9.2 Identification and Control of Items

Except for instances where differences between nominally identical items would have insignificant impact on operations or maintenance, all items, materials, and components shall be uniquely identified. After installation, even identical items shall, in general, be uniquely identified by their installed location when practicable.

The item may be stenciled, engraved, a placard attached, or otherwise encoded as appropriate to the circumstances. Identification shall be accomplished in accordance and be compatible with project naming conventions, applicable industry standards and CMB-S4 Project requirements. If properly cross-referenced to permanent documents and records, vendor identification already placed on the item should be used.

9.3 Item Control and Protection

Items, including consumables, shall be identified, and controlled to ensure their proper use and prevent the use of incorrect, unaccepted, or unidentified items. The project will define a system of controls to ensure that items are handled, stored, shipped, cleaned, maintained, and preserved to prevent them from deteriorating, being damaged, or becoming lost. These controls will be established according to instructions, specifications, drawings, and technical manuals for items that are sensitive, have a high cost, or have been identified as having a significant impact on the environment or schedule.

9.4 Suspect/Counterfeit Items

Suspect and/or counterfeit parts are prohibited. Inspections will be used to detect violations. When suspect/counterfeit parts are found notify the institutional QA manager, and identify, segregate, and dispose of in accordance with DOE G 414.1-3, Suspect/Counterfeit Items Guide (see Appendix for document link).

10 Design Process

The CMB-S4 design shall be defined, controlled, and verified. The design for the CMB-S4 project is defined by the high-level science requirements that flow down to technical requirements and that then flow down into design specifications, drawings and engineering notes. The design output documents are reviewed and approved as documented in the design reviews and change control sections of this QAP. Designs will be verified via design reviews, calculations, analyses, simulations, and testing. A detailed CMB-S4 Systems Engineering Management Plan document is maintained in the DocDB document archive under CMBS4-doc-520.

10.1 Design Inputs

Design inputs are specified in a timely manner and correctly translated into the appropriate design documents. Inputs will include top level physics requirements, life cycle requirements, functional requirements, performance/design parameters, serviceability requirements, appropriate health and safety codes, and reliability requirements. Applicable design inputs shall be identified and documented, and their selection reviewed and approved. Design input shall be specified to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

10.2 REQUIREMENTS

The CMB-S4 registry of all requirements down to the Level 3 level and typically at lower levels is stored and managed using the Jama Connect database tool. Requirements are managed subject to the Project's configuration management policies.

10.3 EHS CONSIDERATIONS

The CMB-S4 project shall conduct and maintain a hazards assessment for the entire CMB-S4 project. Internal reviews shall be conducted on a periodic basis and external reviews shall be conducted at the appropriate critical decision milestone reviews.

As appropriate, an EHS project representative shall attend internal project design reviews to evaluate EHS considerations in the design.

10.4 PERFORMANCE/DESIGN PARAMETERS

Design parameters and Current Best Estimates of instrument performance are recorded in the Jama Connect tool.

10.5 DESIGN INTERFACES

Interfaces within the project are recorded and managed as requirements in the Jama Connect database tool.

10.6 DESIGN OUTPUTS

Output documents shall be prepared to support risk assessments, procurement, fabrication, inspection, assembly, construction, testing, shipping, installation, and commissioning of the CMB-S4 project deliverables. These documents will be stored, reviewed and updated in accordance with Section 7 Change Control. The Level 2 Science Lead, institutional QA representative, and supporting staff shall determine which documents are required for the successful completion of the system deliverables. The Project Engineer, CMB-S4 Project Manager and/or Project Director shall provide concurrence on the design output package. A list of documents which may be employed for use includes:

- Mechanical Drawings
- P&IDs
- Electrical Schematics
- Printed Circuit Board Layouts
- Software Flowcharts
- Test/Inspection Plans or Procedures
- Procurement Specifications
- Technical Specifications
- Technical Reports
- Acceptance Criteria
- Manufacturing Plans
- Assembly/Installation Plans
- Storage Plans
- Shipment Plans

For CMB-S4 project deliverables as-built documentation shall be maintained to show actual configurations.

10.7 DESIGN VERIFICATION

Design verification ensures that the proposed design satisfies the requirements. There are several methods that shall be employed by the project for design verification. These include design reviews, calculations, analyses, simulations, and prototype testing. As part of the graded approach, Level 2 Science Leads,

institutional QA representative, and supporting staff will determine the design verification methods which shall be communicated to the CMB-S4 Project Engineer, Project Manager and/or Director for concurrence. At a minimum, each Level 2/Level 3 system shall have a set of prescribed design reviews as detailed in Section 9.8 Design Reviews.

The particular design verification methods used shall be identified and documented in the Jama Connect requirements database with their associated requirements. The results of the design verification shall be documented with the identification of the verifier clearly indicated. Design verifications shall be performed by technically knowledgeable individuals. If a design is modified to resolve verification findings, the modified design shall be verified prior to release for use.

10.8 CONSTRUCTABILITY OR PRODUCIBILITY

Constructability and producibility is the quality element that relates to the ease with which the component can be built, manufactured, assembled, inspected, and tested using readily available techniques, materials and components. This is especially important to reduce risk, construction or manufacturing complexity, and life cycle support complexity. Using approaches, such as elimination (parts, functions, characteristics), design simplification, standardization, and minimization of production and handling operations may increase the constructability or producibility of components.

Whenever possible, the Project should use materials and components that have already demonstrated their ability to be used in the same environmental conditions and submitted to the same functioning constraints.

10.9 DESIGN REVIEWS

For build-to-specification procurements, design reviews of the manufacturer's design phases may be required before approving continuation of the fabrication. Contracts may include the provision of passing such a review before further expenditure.

Technical design reviews shall be conducted in order to ensure the final design and supporting documentation will meet all the relevant project requirements. The Project Engineer will determine the appropriate breakdown and timeline for design reviews. In general, each major WBS Level 2/Level 3 element will undergo a review at the following design maturity stages:

- Conceptual Design Review (CDR)
- Preliminary Design Review (PDR)
- Final Design Review (FDR)
- Procurement Readiness Review (PRR)
- Manufacturing Readiness Review (MRR)
- First Article Inspection (FAI)
- Factory Acceptance Testing (FAT)

The Procurement Readiness Reviews (PRR) shall be conducted at the discretion of management and may be required by the L1 Manager if a WBS element scope includes a major procurement. A procurement is considered major if the risk level is High or Very High per Table 2.

Manufacturing Readiness Reviews (MRR) shall be conducted at the discretion of management before release of project-designed hardware documentation packages for vendor quotations and fabrication.

Details regarding execution of design reviews are documented in CMBS4-doc-673. Each design review shall have a formal charge letter to define the review scope. In response to this letter, a review committee shall identify strengths and weaknesses of the reviewed WBS element(s) and provide actionable feedback the project can use to rectify any problem areas. These review committees may include either a fully internal panel of project team members or a mix of both external & internal reviewers. External reviewers are invited to serve on review committees as part of the graded approach, at the discretion of the CMB-S4 project office, when the internal expertise of the project collaboration is determined not to be sufficient to effectively evaluate status.

All review committee recommendations are tracked for responses/actions by the project. These recommendations are also reviewed at subsequent design reviews for closure and/or progress.

10.10 COMPUTER MODELING AND PERFORMANCE PREDICTION

Computer programs used to provide data that serve as the design basis of a structure, system, or component will be verified and validated. The verification process will demonstrate that the computer program produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. The validation process is to show that the encoded mathematical model produces a valid solution to the physical problem associated with the particular application.

The design of software and controls is driven by a set of general guidelines to improve reliability and maintainability:

- The use of industry components and standards;
- An architecture based on well-established practices and design patterns;
- The validation of the technical platform and architecture through prototyping and incremental delivery;
- A model-based development approach integrated with an Agile management process;
- The efficient support and collaboration with the parties involved in the development of the different subsystems;
- Manages software source code, releases, and issue tracking.

The purpose of the Software QA process is to provide assurance that work products and processes comply with predefined provisions and plans. The quality assurance process is coordinated with the related Software Verification, Software Validation, Software Review, Software Audit, and Software Problem Resolution processes.

10.11 CONFIGURATION CONTROL AND CONFIGURATION MANAGEMENT

Design changes, including field changes and inadvertent changes (e.g., nonconformance disposition as “Use-as-Is” or “Rework”) shall be controlled by measures commensurate with the original design. For example, if design verification has been completed on the original design, then any design change associated with that item will require additional design verification. Change control shall include evaluation of effects of the changes on the overall design and on the analyses upon which the design is based.

If a significant design change is necessary because of an incorrect design, then the design process and verification procedures used shall be reviewed and modified as necessary. The configuration of the instrument shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the instrument. The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation.

11 PROCUREMENT

Procurement controls will be implemented to ensure that purchased items and services meet project needs and comply with applicable quality requirements. Each lead institution’s QAP will be implemented for procurements made by that institution; however, the basic requirements of the CMB-S4 quality plan must still be met.

For the CMB-S4 project three levels of procurements have been established as part of the graded approach for the CMB-S4 quality program. The levels and criteria are listed below:

- Major Procurements: These procurements are typically for highly customized and complex components with a cost of greater than $500k. Most importantly a major procurement is usually critical to the project success and has the potential to greatly impact project cost/schedule. The Project Manager and Project Director along with the Project Engineer shall determine which procurements qualify as major.
- Custom Procurements: These procurements are typically for custom components with a cost of less than $500k. An issue with a custom procurement may cause a temporary delay but can be recovered from without significant impact to the overall project progress.

- Catalog Items: These procurements are for standard components that are available to order from a supplier's published catalog.

11.1 SUPPLIER SELECTION, EVALUATION & MANAGEMENT

Potential suppliers of major procurements, prior to award, shall be evaluated to ensure they have the capability to provide the items or services in conformance with the technical and quality requirements of the procurement. The determination of which suppliers shall be evaluated shall be made by the CMB-S4 project technical personnel, in conjunction with the appropriate institutional procurement personnel.

A supplier's evaluation may be based upon the results of one, or a combination of, the following:

- Supplier bid response and bid package completeness
- Supplier manufacturing/verification equipment and capabilities
- Supplier quality evaluation survey
- Supplier onsite visit with review of supplier's quality history
- Review of supplier references for similar projects
- Assessment of supplier's proposed subcontractors, if any

Ongoing evaluation and management of supplier performance shall be performed for both major and custom procurements. This shall help ensure technically acceptable components are delivered and the supplier continues to meet all quality, technical, delivery and other performance requirements. Unacceptable items or services for all procurements shall be documented and corrective actions shall be implemented in accordance with purchase order conditions should a supplier not perform as required.

Some methods of supplier management that may be employed are listed below. The relevant Level 2 Science Lead/technical lead shall determine which methods are appropriate for an individual procurement. Requests for vendor proposals and procurement contracts should include explicit provisions for these kinds of engagement between the project and the vendor, at the project's discretion.

- Periodic phone conferences
- Periodic supplier reporting - status, schedule, photos
- Regular on-site visits
- Supplier manufacturing plan & evaluation
- Raw material certifications, inspections, testing
- First article sampling & inspection
- Production sampling & inspection
- On-site test and verifications
- Supplier in-process inspection & testing
- Supplier post fabrication inspection & testing
- Supplier packaging/shipping plan & evaluation
- First Article Inspection (FAI)
- Factory Acceptance Testing (FAT)

11.2 PROCUREMENT DOCUMENTS

CMB-S4 personnel requesting procurement of items and services are responsible for providing technical, EHS and other specifications that adequately describe the item or service being procured so that the supplier can understand what is required of them and what will be accepted.

The following factors should be considered when creating procurement specifications:

- Technical performance requirements
- Compliance to appropriate industry standards
- Laws and regulations
- Acceptance criteria & verification procedures
- Inspection requirements
- Supplier management requirements
- Vendor qualifications and certification requirements

- EHS requirements and hazard mitigations
- Handling and cleanliness requirements
- Shipping and packaging requirements
- Documentation packages required from the vendor

Quality requirements that become part of the procurement specification/documents are selected based upon the graded approach. The graded approach is used to ensure that only those requirements necessary are selected, i.e., requirements that may incur a cost are selected based on the mitigation of programmatic and EHS concerns.

As mentioned above the CMB-S4 project has established 3 procurement levels to ensure an appropriate level of quality is applied. The list below details the decision authority for each procurement level.

- Major Procurements - As mentioned in the design review Section 9.9 above, major procurement packages may be subject to a Procurement Readiness Review. In the absence of a PRR the Level 2 Science Lead, Project Engineer and Quality Assurance Manager shall evaluate the adequateness of the procurement documentation package.
- Custom Procurements - For custom procurements, the Level 2 or Level 3 Manager shall determine the required procurement documents and associated quality requirements.
- Commercial/Catalog Item - Typically no documents required, Level 3 Manager shall determine quality requirements.

For all procurements, counterfeit and/or suspect parts are prohibited. Inspections will be used to detect violations. When counterfeit/suspect parts are found, they will be reported, identified, segregated, and disposed of in accordance with DOE G 414.1-3, "Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1D, Quality Assurance" (see Appendix for document links).

11.3 PROJECT TEAM MANUFACTURING

Several subsystems within the CMB-S4 project will be fabricating and or integrating components in house for the CMB-S4 experiment. Quality controls shall be established to ensure these activities and components meet project needs and comply with applicable project requirements.

For the CMB-S4 project, three levels of manufacturing have been established as part of the graded approach for the CMB-S4 quality program. The levels and criteria are listed below:

- Production Manufacturing: Fabrication of more than several (~20) substantially similar items that are project deliverables shall typically be considered production manufacturing. The CMB-S4 Project Manager and Project Engineer shall help Level 2 Science Leads determine which items are considered production fabrications for the CMB-S4 project.
- Non-Production Manufacturing: Fabrication of fewer than approximately 20 substantially similar items. The finished product shall be deliverable as part of the CMB-S4 project.
- Prototype or R&D Fabrication: These components and activities are for research, development, and prototyping efforts only. The finished product of these fabrications will not be part of the deliverable CMB-S4 project.

The following factors should be considered as part of the manufacturing planning process:

- Technical performance requirements
- Compliance to appropriate industry standards
- Laws and regulations
- EHS requirements
- Assembly procedures
- Verifications (Inspections) & Acceptance Criteria
- Testing requirements
- Handling and cleanliness requirements
- Shipping and packaging requirements
- Storage requirements
- Commissioning requirements

- Documentation deliverables

As mentioned above the CMB-S4 project has established 3 manufacturing levels to ensure an appropriate level of quality is applied. The list below details the decision authority for each manufacturing level.

- Production Manufacturing - For production manufacturing, the Level 2 Science Lead, Project Engineer and Quality Assurance Manager shall evaluate the adequateness of the manufacturing documentation package. A Manufacturing Readiness Review may be convened at the request of the Project Manager and/or Project Engineer to review the manufacturing readiness.
- Non-Production Manufacturing - For custom procurements the Level 2 Science Lead shall determine the required manufacturing documents and associated quality requirements.
- Prototype or R&D Fabrication - For catalog items the Level 3 Manager shall determine the required manufacturing documents and quality requirements, if any.

12 VERIFICATION & ACCEPTANCE TESTING

The implementation of testing procedures and establishment of acceptance criteria are important elements of the CMB-S4 project QAP. This applies to both outsourced procurements and fabrication activities performed by project personnel.

Level 2 Science Leads shall ensure that any in-house work along with procured components requiring formal inspection and acceptance testing is identified. Special attention should be paid to ensure all essential safety items or systems that require formal inspection and testing are identified.

12.1 INSPECTION

Project management and Level 2 management determine when inspections and tests are necessary to determine the quality of a process or product. The overall strategy for acceptance testing will be established within the Acceptance Criteria Strategy (ACS) document. Inspection travelers, test plans, method details will be identified within the ACS. Such inspections and tests should be conducted in a manner that assures conformance to the established criteria. The results of inspections and tests are used as a basis for acceptance by a comparison with approved acceptance criteria provided or referenced by the purchase order or other documentation. The signature of the responsible individual indicates acceptance of inspection and test results. The LBNL or partner institution QAR is responsible for assuring that the verification items identified within the ACS are satisfied, and the appropriate documents captured.

If source inspection is performed at supplier facilities, the surveillances shall be performed at intervals consistent with the importance and complexity of the item or service. Source inspection includes monitoring, witnessing, or observing selected activities. Previously identified vendor corrective action may also be witnessed. Upon acceptance of the item during source inspection, evidence of acceptance of source verification shall be documented. Acceptance of an item during source surveillance does not relieve the Supplier of its quality responsibilities.

If receiving inspection is used, purchased items shall be inspected by qualified staff as necessary to verify conformance to specified requirements. Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional; physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be provided prior to receiving inspection.

Acceptance of services, such as third-party inspection services or engineering and consulting services shall be by one of the following methods:

- Technical verification of data produced;
- Surveillance and/or audit of the activity;
- Review of objective evidence for conformance to the procurement document requirements.

Tests required to verify conformance of an item to specified requirements and/or to demonstrate that items will perform as intended in service are planned and documented in test plans, procedures or instructions. The characteristics to be verified or tested and the methods to be employed are specified. Test results are

to be documented as specified in the test specification documents. Results of tests performed to verify designs are reviewed and evaluated by the Level 2 Science Lead. Results of tests performed to verify conformance to specified requirements are reviewed and evaluated by the Lead Systems Engineer or Level 2 Systems Engineer.

12.2 ESTABLISHMENT OF ACCEPTANCE CRITERIA

Level 2 Science Leads along with the appropriate technical personnel (and in some cases the Project Office) shall develop acceptance criteria. These criteria shall provide verification that components/assemblies meet relevant technical and scientific project requirements.

12.3 VERIFICATION PLANS – TEST & ACCEPTANCE PROCEDURES

Verification plans shall indicate the inspection or acceptance testing to be performed. The inspection techniques to be used will be defined and documented via a test or acceptance procedure. Per the graded approach, these documents shall be reviewed to ensure the detail in documenting these procedures is commensurate with complexity and scope of the testing. Designated inspection/tests shall be performed using equipment that is calibrated and maintained.

12.4 CONTROL OF MONITORING AND MEASURING DEVICES

Monitoring and measurement devices require evidence of conformity to known and accepted reference standards. It is the responsibility of project line managers to ensure that equipment is appropriately calibrated. When necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards or to a defined basis, where no such standard exists;
- Adjusted as necessary;
- Identified to display the calibration status;
- Safeguarded from adjustments that would render the measurement invalid;
- Protected from damages and deterioration.

In addition, CMB-S4 assesses and records the validity of previous measuring results when the equipment is found not to conform to requirements. CMB-S4 takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained. Defective equipment shall be removed from service and identified accordingly.

When used in the monitoring and measuring of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This shall be performed prior to the initial use and reconfirmed as necessary.

12.5 HANDLING, STORAGE, AND TRANSPORTATION

All packaged items shall be protected against the environment (including vibration, shock, dust, precipitation, and extreme temperatures) as specified in the SOW or on any additional special environmental requirements specified by the contractor. The contractor is responsible for providing verifiable evidence that the protective barriers and transportation methods satisfy the environmental requirements (e.g., including shock indicators or calibrated data loggers).

12.5.1 BY CONTRACTOR

Procedures for handling, storage, and transportation are the responsibility of the contractor and will be submitted for review and acceptance by the Project before it occurs.

At the time of inspection, CMB-S4 staff shall verify the effective implementation of the applicable handling, storage, and transportation procedures.

12.5.2 BY CMB-S4 IN-HOUSE

Procedures for handling, storage, and transportation of in-house project parts and equipment are the responsibility of L2 Manager in accordance with the CMB-S4 Project handling, storage and transportation requirements established by the Project Office.

13 NON-CONFORMANCE AND CORRECTIVE ACTION

Non-conforming items and services are defined as components or processes that do not meet established or agreed upon requirements or do not result in the anticipated quality as specified in the requirements. This section describes the necessary actions to identify and control non-conformances and how to apply corrective actions to remedy the quality failure.

Each institution shall provide a systematic approach to the identification, segregation, reporting, review, analysis, corrective action, and re-verification of nonconformance issues. This includes effective labeling and segregation of affected parts so that they are not accidently used in the system being delivered. The institution's quality plan shall describe the control processes, including identifying the persons or groups responsible for decisions. Complete records are required of any action or decision made regarding the nonconformance and may be requested during audit or review.

Corrective actions will be taken when identified quality non-conformances exceed predefined acceptability limits, when they deviate from required procedures, when they fail to meet requirements or specifications, especially in the areas that affect safety and reliability.

Corrective actions should identify the affected products so that a decision can be made on whether to accept the product and waive the non-conformance, repair the product, or initiate disposal. The general steps of a corrective action procedure are as follows:

- Review and document the problem;
- Contain or temporarily fix the problem;
- Investigate the cause and determine its root cause;
- Propose an appropriate solution that will prevent the problem from reoccurring;
- Assess the impacts of the proposed solution;
- Implement the solution and report on the actual actions taken;
- Assess the success of the corrective actions and document it; and
- Close the issue when the problem is resolved.

Records of the corrective actions shall be taken and must include traceability of a waived or repaired non-conforming part to include it in its lifecycle history.

14 ACCEPTANCE AND DELIVERY

14.1 ACCEPTANCE PROCESS

All hardware, software, and deliverable acceptance procedures shall be defined in the respective ACLs.

The acceptance may be conditional on information relevant to the configuration, integration, and test operations performed on the system, the completeness of the deliverables, and on any documented change requests, waivers, or non-conformances.

The acceptance conditions shall be updated if any modifications were made to the pre-accepted system after delivery.

14.2 HANDLING, STORAGE, AND TRANSPORTATION

All packaged items shall be protected against the environment (including vibration, shock, dust, precipitation, and extreme temperatures) or on any additional special environmental requirements. Verifiable evidence that the protective barriers and transportation methods satisfy the environmental requirements (e.g., including shock indicators or calibrated data loggers) is required.

At the time of inspection, the receiving entity will verify the effective implementation of the applicable handling, storage, and transportation procedures.

15 PROJECT MANAGEMENT ASSESSMENTS

15.1 PROJECT REVIEWS

The CMB-S4 Project Director is committed to an on-going program of project reviews. Results of project reviews will be used to identify, correct, and prevent management problems that hinder the achievement of the project's objectives.

Reviews and audits shall be used as tools to provide a check of the quality of work being performed both internally and externally by contractors.

The subject of the review can be selected from a broad range of topics, from top-level system to high-risk components, and from both the technical and managerial sides of the Project. However, in each case, objective evidence is required to prove that the product, service, or organization is meeting the requirements as agreed. Depending on the criticality of the subject of the review or audit, an independent assessment by industry experts may be required.

15.2 PROJECT MANAGEMENT ASSESSMENTS

The Project Director prepares a monthly report summarizing the status of the project. Each Level 2 Science Lead submits a summary of their work for assessment by the Project Manager.

Level 2 subsystems within the CMB-S4 Project are discussed and reviewed by the Project Management Team during the research & development phase through periodic meetings. These meetings encompass the scope, technical specifications, procedures, budget, schedule, and safety of the plans for constructing the subsystem. Level 2 Science Leads also typically hold weekly meetings to cover all of the above issues. A graded approach is then used to determine which subsystems need more formal reviews as described below.

As mentioned in the Procurement & Manufacturing sections of this QAP, when appropriate, the Project Director and/or Level 2 Science Leads organize Procurement Readiness Reviews and Manufacturing Readiness Reviews prior to full production of components. These reviews include design documentation, manufacturing plans, quality assurance plans, quality control methods, information compiled during R&D activities, and data collected from prototype components.

Additional reviews and workshops may be organized on an ad hoc basis for selected technical systems and components, e.g., electronics cards or software. Such reviews are organized by the CMB-S4 Project Manager and may include the Project Engineers, the Level 2 Science Lead(s), and technical experts from the CMB-S4 collaboration and/or external experts. The Project Director also has the authority to form an ad hoc review team to investigate quality assurance or quality control non-conformances if the need arises.

This QAP will also be reviewed on a minimum of an annual basis by the project management team to ensure its continued effectiveness and implement improvements as needed.

15.3 AUDITS

Quality assurance audits shall be performed to ensure that the appropriate systems not only are in place but are being followed to provide the agreed upon level of quality.

Depending on the criticality of the product, service, or organization being audited, CMB-S4 may elect to use an external and independent team of experts to perform the process. For external audits, it must be ensured that contracts contain language that allows Quality Audits to be performed at any time during the contract.

Conformance Audits: focus on the ability of the contractor or its subcontractors to meet the agreed upon requirements on the system being implemented. The audit team may also request to witness live processes to verify that quality systems are being employed as stated in the contract.

Compliance Audits: are performed to ensure that the contractor is meeting the legal and regulatory requirements, such as safety requirements. Follow-up audits may be required to validate the effectiveness of any applied corrective actions.

16 INDEPENDENT ASSESSMENT

Independent assessment of the CMB-S4 Project comes from several sources. These include periodic Integrated Project Team meetings with the Department of Energy and National Science Foundation and more formal Independent Project Reviews on a periodic basis. These assessments measure item and service quality, judge the adequacy of the work performance, and are used to promote improvement.

This QA Program is part of the overall Project implementation and is assessed as part of the planned reviews conducted by the LBNL Directorate and selected DOE and NSF representatives. It is the responsibility of the Project Manager to ensure the information necessary for the review is available and that knowledgeable personnel are available to present material to the review committees.

APPENDIX A – GOVERNING DOCUMENTS

DOE O 414.1D

https://www.directives.doe.gov/directives-documents/400-series/0414.1-border-d-ltdchg2

Title: Quality Assurance

Description: To ensure that Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' requirements and expectations. To achieve quality for all work based upon the following principles: (1) All work, as defined in this Order, is conducted through an integrated and effective management system; (2) Management support for planning, organization, resources, direction, and control is essential to quality assurance (QA); (3) Performance and quality improvement require thorough, rigorous assessments and effective corrective actions; (4) All personnel are responsible for achieving and maintaining quality; and (5) Risks and adverse mission impacts associated with work processes are minimized while maximizing reliability and performance of work products. To establish additional process-specific quality requirements to be implemented under a Quality Assurance Program (QAP) for the control of suspect/counterfeit items (S/CIs), and nuclear safety software as defined in this Order.

DOE G 413.3-2

https://www.directives.doe.gov/directives-documents/400-series/0413.3-EGuide-02

Title: Quality Assurance Guide for Project Management

Description: This Guide provides acceptable approaches for implementing the Quality Assurance requirements and criteria of DOE O 413.3A related to the development and implementation of a Quality Assurance Program for the project. No cancellations.

SUBPART A – QUALITY ASSURANCE REQUIREMENTS

https://www.ecfr.gov/current/title-10/chapter-III/part-830/subpart-A

DOE G 414.1-2B

https://www.directives.doe.gov/directives-documents/400-series/0414.1-EGuide-2Badmchg1

Title: Admin Chg 1, Quality Assurance Program Guide

Description: This Guide provides information on principles, requirements, and practices used to establish and implement an effective Quality Assurance Program. Cancels DOE G 414.1-2A, DOE G 414.1-3 and DOE G 414.1-5.

DOE G 414.1-4

https://www.directives.doe.gov/directives-documents/400-series/0414.1-EGuide-4

Title: Safety Software Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance

Description: This Guide provides acceptable methods for implementing the safety software quality assurance requirements of DOE O 414.1C, Quality Assurance.

DOE O 243.1B

https://www.directives.doe.gov/directives-documents/200-series/0243.1-BOrder-b

Title: Records Management Program

Description: The order sets forth requirements and responsibilities for creating and preserving records of DOE organization, functions, policies, decisions, procedures, and essential transactions and information

necessary to protect the legal and financial rights of the Government and persons directly affected by DOE activities.

DOE P 450.4 A

https://www.directives.doe.gov/directives-documents/400-series/0450.4-APolicy-a

Title: Integrated Safety Management Policy

Description: The policy establishes DOE's expectation for safety, including integrated safety management that will enable the Department's mission goals to be accomplished efficiently while ensuring safe operations at all departmental facilities and activities. Supersedes DOE P 450.4, DOE P 411.1, DOE P 441.1, DOE P 450.2A, and DOE P 450.7

DOE G 414.1-3

https://www.directives.doe.gov/directives-documents/400-series/0414.1-EGuide-3

Title: Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance

Description: This Guide provides guidance to assist DOE/NNSA and its contractors in mitigating the safety threat of suspect/counterfeit items (S/CIs).

LBNL PUB-3111

https://commons.lbl.gov/download/attachments/77332681/PUB+3111+OQMP.pdf

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