Atacama Large Millimeter / submillimeter Array

ALMA

Product Assurance Requirements

ALMA-80.11.00.00-001-D-GEN

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CHANGE RECORD

Rev	Date	Pages	Change Request Number	Comments
A	2003-AUG-21	0		Initial Release
B	2003-DEC-14	Sect 3.1		Updated applicable docs table:
C	2004-JUN-28	Sect 3.1	ALMA-80.03.00.00-006-A-CRE	Updated applicable docs table: Versioned upward AD 1,2,3,4,6
D1	2008-JAN-24	Sect 1, 4	Interim change (not submitted to DAR)	Add information about SE IPT and tailored PA Plans.
D2	2008-NOV-22	All	Interim change (not submitted to DAR)	Update date formats, add some process flow diagrams.
D3	2009 –MAR-30	All	Interim change (not submitted to DAR)	Add new corrective action process, AI tracking, Auditing processes.
D4	2009-APR-07	All	Interim change (not submitted to DAR)	Modify requirements to reflect current practices. Add new process areas. Add process mapping diagrams.
D5	2009-MAY-11	All	Interim change (not submitted to DAR)	Elaborate existing process areas, update flow diagrams. Submit for SE review.
D6	2009-MAY-12	All	Interim change (not submitted to DAR)	Incorporate RM comments. Add handover guidelines. Submit to for PA team review.
D7	2009-MAY-25	All	Interim change – awaiting DAR review.	Incorporate PA team comments, BT comments, MH comments, MS comments. Submit to DAR for project level review.
D8	2009-AUG-29	All	Interim change – after DAR review	Incorporate reviewer comments from the DAR review.
D9	2009-SEP-22	Sect 11	Interim change – after DAR review	Elaborate TRR, PAI, PAS process and responsibilities.
D10	2009-OCT-19	Sect 3, 6, 9	Interim change – after DAR review	Incorporation of final comments and correction of typos prior to formal release.
D11	2009-DEC-03	Sect 1, 4,7,9,10	Interim change after DAR review	Incorporation of additional September comments (GHT) and comments from external auditor (HJ).
D12	2009-DEC-10	Sect 11	Interim change after DAR review	Additional comments from GHT incorporated.
D13	2010-JAN-22	Sect 1,2,4,6,10,11,12, 14,20,22	Interim change after CCB review	Incorporation of January WW comments.
D	2010-JAN-27	All	ALMA-80.11.00.00-32-C-CRE	Release to CCB after DAR approval of all Revision D updates.

1 INTRODUCTION

This document defines the Product Assurance (PA) requirements for the Atacama Large Millimeter/submillimeter Array (ALMA) system project. The purpose of these requirements is to ensure that all components of the ALMA system are delivered with a consistent high level of quality in their design, fabrication, performance, reliability and documentation. This is essential to make sure the ALMA system is able to operate to its required performance levels over its intended operational lifetime.

The ALMA project is comprised of a consortium of laboratories and organizations in countries all around the world. For the purpose of this document, the word 'consortium' is defined as: "A cooperative arrangement among groups or institutions" and refers collectively to all organizations involved in the ALMA project.

This document identifies a set of PA requirements applicable to all organizations within the ALMA consortium including subcontractors and suppliers. It is incumbent upon each organization to ensure that all aspects of these product assurance requirements are addressed throughout the execution of their work or the work of their subcontractors and suppliers. When necessary, the requirements specified in this document may be elaborated or tailored by an IPT or subcontractor level Quality Plan reviewed by JAO PA and approved by the IPT. In case of conflict between this document and an existing, signed contractual agreement between an Executive and a contractor, the existing contract will have precedence.

2 SCOPE

These requirements cover PA activities related to the specification, design, procurement, manufacture, delivery and acceptance of every hardware and software item under configuration control that is required for completion of the ALMA system. In cases of conflict between this document and Executive procurement rules, the existing Executive rules will have precedence.

If development efforts have already passed the time frame when a PA deliverable is required, the Integrated Product Teams (IPTs) are not required to submit those deliverables unless there are future PA requirements that are dependent on the creation of a particular document or procedure.

The requirements contained in this document are not applicable to items intended for common project activities such as general-use computers and software, furniture or phone systems that are not required for the scientific capabilities of the telescope. This exclusion does not include safety, civil infrastructure and facilities which are important to the array operations.

3 RELATED DOCUMENTS AND DRAWINGS

The following subsections specify documents that are applicable to this document to the extent specified.

In the event of a conflict between the information contained in this document and the information contained in a referenced document, the information in this document supersedes the information from the referenced document.

3.1 Applicable Documents

The documents listed below form a part of this document to the extent specified and described herein.

Applicable Document List		
Reference	**Document Title**	**ALMA Doc. Number**
AD1	ALMA Operations Plan	ALMA-00.00.00.00-002-D-PLA
AD2	ALMA Project Plan	Version III – May 7, 2009
AD3	ALMA Design Reviews Definitions, Guidelines and Procedure	ALMA-80.09.00.00-001-D-PLA
AD4	ALMA Documentation Control Plan	ALMA-80.02.00.00-011-F-PLA
AD5	ALMA Documentation Standards	ALMA-80.02.00.00-003-G-STD
AD6	ALMA PA Staffing Plan	ALMA-80.11.00.00-025-D-PLA

Table 1: Applicable Documentation

3.2 Reference Documents

The following documents are referenced in this plan and are used for guidance and information only.

Reference Document List		
Reference	**Document Title**	**ALMA Doc. Number**
RD1	Sampling Procedures and Tables for Inspection by Attributes	ANSI/ASQC Z1.4-1993
RD2	ALMA Handover Form - Template	ALMA-80.11.00.00-031-A-GEN
RD3	ALMA General safety design specification	ALMA-10.08.00.00-003-B-SPE
RD4	ALMA Safety Risk Analysis Procedures	ALMA-10.08.00.00-004-A-GEN
RD5	ALMA System Electrical Design Requirements	ALMA-80.05.00.00-005-C-SPE
RD6	ALMA System Electromagnetic Compatibility (EMC) Requirements	ALMA-80.05.01.00-001-B-SPE
RD7	ALMA Environmental Specification	ALMA-80.05.02.00-001-B-SPE
RD8	ALMA Interface Management Plan	ALMA-80.07.00.00.001-D-PLA
RD9	ALMA Power Quality Specification	ALMA-80.05.00.00-001-B-SPE
RD10	Standard for Plugs, Socket-outlets, and Couplers	ALMA-80.05.00.00-004-B-STD
RD11	ALMA Guidelines for Identification and Labeling of ALMA Components	ALMA-80.02.00.00-016-A-SPE
RD 12	ALMA System Technical Requirements	ALMA-80.04.00.00-005-B-SPE

Table 2: Reference Documentation

3.3 Abbreviations and Acronyms

The list of acronyms and abbreviations used in this document are defined below.

Abbreviation or Acronym	Non-abbreviated Reference	Abbreviation or Acronym	Non-abbreviated Reference
ACRV	Acceptance Review	MIPT	Management IPT
ADP	Acceptance Data Package	MOU	Memorandum of Understanding
AI	Action Item	MRB	Material Review Board
AIPC	Acceptance In Place, Chile	MRR	Manufacturing Readiness Review
ALMA	Atacama Large Millimeter Array	NA	North America
ANSI	American National Standards Institute	NCR	Non-Conformance Report
ASQC	American Society for Quality Control	ORR	Operational Readiness Review
CAR	Corrective Action Request	PA	Product Assurance
CCB	Configuration Control Board	PAI	Preliminary Acceptance In-house
CDMR	Critical Design and Manufacturing Readiness	PAS	Provisional Acceptance on-Site
CDR	Critical Design Review	PCB	Printed Circuit Board
CI	Configuration Item	PDR	Preliminary Design Review
CIDL	Configuration Item Data List	PMCS	Project Management Control Schedule
CMMS	Computerized Maintenance Management System	PPDR	Pre Production Design Review
COTS	Commercial Off The Shelf	PTR	Post Test Review
CRE	Change Request	RFW	Request for Waiver
DAR	Document Approval Request	SA	South America
EMC	Electromagnetic Compatibility	SE	System Engineering
EU	European Union	TBD	To Be Determined
IPT	Integrated Product Team	TRR	Test Readiness Review
JAO	Joint ALMA Observatory		
JIRA	Not an acronym. Name of issue tracking tool.		

Table 3: Acronyms

3.4 Definitions

Acceptance data package: All documentation required to completely define the "as-built" version of the delivered equipment. Including, but not limited to, the documents detailed in Section 11 of this document.

Acceptance Review: A formal project level (involving multiple IPT and JAO participants) evaluation of all work products associated with delivery of ALMA subsystem components. The ACRV follows the typical acceptance guidelines and is more comprehensive than a typical PAS event, used primarily for components assembled in Chile that do not have a PAI at a vendor location.

Acceptance Test and Inspection: Tests and inspections performed on a deliverable item to ensure it satisfies the applicable requirements, a subset of verification tests. The distinction between verification tests and acceptance tests is typically described in a Verification and Acceptance Plan.

Approved Work Product: Refers to documentation, product material, software components, etc. that have completed required reviews and are ready for final "release" (see Release definition below).

Baseline Configuration: The complete description of a deliverable system or subsystem describing the snapshot of the configuration with a listing of all parts and documentation, including versions, of internal components at the time of delivery. Usually accomplished by submitting a CIDL (see description below) with the delivered material at the time of acceptance. The baseline configuration may contain as-built drawings, but there would be an associated AI to track update of the drawing or a waiver if it is not to be updated.

Change request: Written request to change the content of a controlled document.

Conditional Acceptance: The status granted by the receiving party or customer, usually the JAO, allowing delivery of unverified or non-compliant work products in an effort to facilitate further testing and design verification/adjustment in a more suitable environment. Conditionally accepted work products must complete the ALMA acceptance process prior to shipping for identification of non-compliance or unverified requirements, and must achieve full final acceptance prior to handover to the observatory.

Configuration item: A hardware or software item that is uniquely defined by its own set of requirements.

Configuration Item Data List: Identifies the applicable issue/revision of requirements documents, specifications, drawings and engineering lists that represent the "as-built" configuration baseline. It includes a section called Change/Waiver Status which identifies the status of approved changes and waivers.

Critical Item: Items, components, modules or subassemblies, which if failed, will cause a failure in the larger assembly of which they are part of.

Custom engineered equipment: Any single component which has been uniquely engineered for ALMA or any integrated assembly, consisting of multiple commercial components, which has been designed specifically for ALMA.

Engineering Model: Work Products accepted conditionally that are approved for use in the observatory prior to handover with the goal of more thoroughly verifying requirements. Engineering Models must complete the ALMA acceptance process prior to handover to the observatory, or be replaced with a fully compliant unit.

Essential equipment: Any piece of hardware or software, the failure of which, results in deterioration in the observational capability or the data processing capacity of the telescope.

Owner: The organization (company, institute, etc) whose is currently responsible for the safeguarding of a configuration item.

Preliminary Acceptance In-house: The PAI event is an evaluation performed at the vendor site to authorize delivery of components to the customer. The event typically involves the vendor performing full acceptance verification, as defined between vendor and customer at the TRR, to verify compliance with requirements, with possible witnessing and data and documentation review by the customer. After completion of the event a report or minutes generated by the acceptance team, listing Action Items is delivered to the management of the customer with a recommendation for delivery of materials.

Preproduction Unit: A deliverable unit or set of units identified by an agreement between the IPT and the JAO that will be delivered prior to a formal design review, but is intended to meet all currently approved requirements at the time of delivery. The goal of a preproduction unit is to transition for a formally unit after approval of the design. In some cases the unit may require rework and re-delivery as a production unit.

Prototype Unit: A unit delivered as a test platform or that is known to contain design questions or issues, but is needed to facilitate the verification of requirements or testing of a higher assembly. A prototype is not formally handed over to the project will require replacement with a production unit.

Provisional Acceptance on-Site: The PAS event is an evaluation performed at the customer site to verify functionality of delivered components and survival of the shipping and transport process, or after the integration process. The inspections and testing are typically performed by the customer. After successful completion of the event, a report, prepared by the acceptance team is delivered to the management of the customer with a recommendation for formal handover.

Released Work Product: All documentation, product material or software that has successfully completed the approval process, including QA review, submission to configuration management system, and tagging of superseded items. A final step to

release is to verify distribution of the newly released work product to vendors or other "customers" holding superseded material.

Reliability Analysis: An analysis performed to determine the expected reliability of the item being designed.

Request for waiver: Written request to use or release product which does not conform to the specified requirement.

Verification and Acceptance Plan: A plan that details how each of the applicable requirements shall be verified. Typical methods include: Test, Analysis, Inspection and Simulation. It also defines the tests needed for verification and the subset of tests performed for acceptance.

Verification Test: Tests performed on initial production version of an item being designed to verify it meets its design requirements.

4 PRODUCT ASSURANCE MANAGEMENT

Responsibility for the ALMA Product Assurance effort is distributed over the same organizational structure as the rest of the ALMA project.

The focus of the ALMA PA activity begins with the ALMA PA Manager and the JAO PA Manager positions both report directly to the Project Engineer (JAO) and indirectly to the ALMA project management. There are full time PA personnel within each executive reporting directly to the ALMA PA Manager (Europe, Chile, North America, ALMA-J). This structure is detailed in Figure 1.

Figure 2 provides a general overview of how the PA responsibility is distributed across the ALMA organization within the IPT's and ALMA-J. The solid lines indicate a direct reporting relationship and the dashed lines denote an advisory relationship.

The PA Principal for each IPT may, in reality, be multiple persons. The decision of the number of PA Principals required for each IPT should be based on the number of physical locations where equipment procured from contractors/vendors will be delivered for integration. Figure 2 provides a detailed picture of the organizational structure.

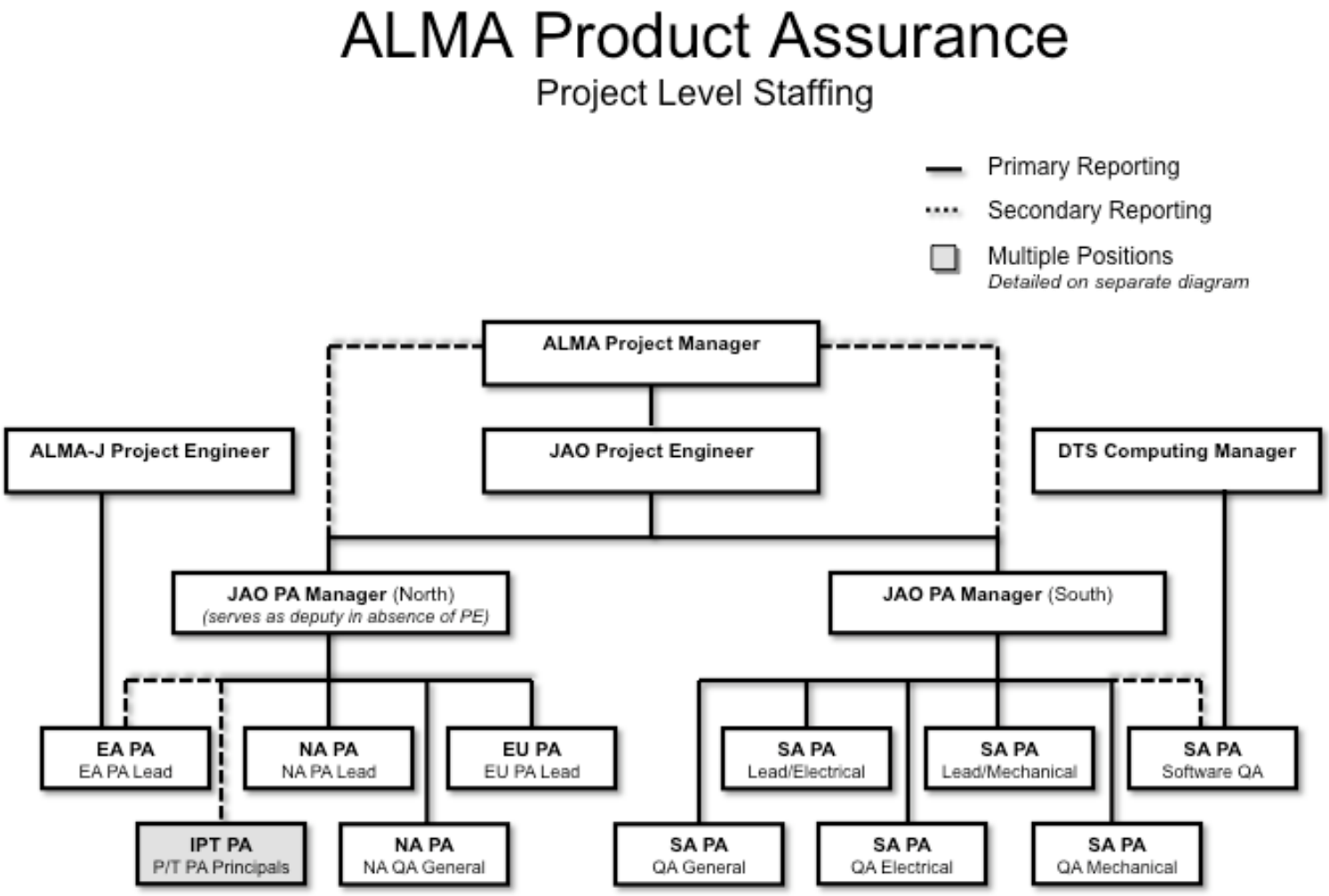

Figure 1: ALMA Product Assurance Organizational Structure – Project Level Staffing

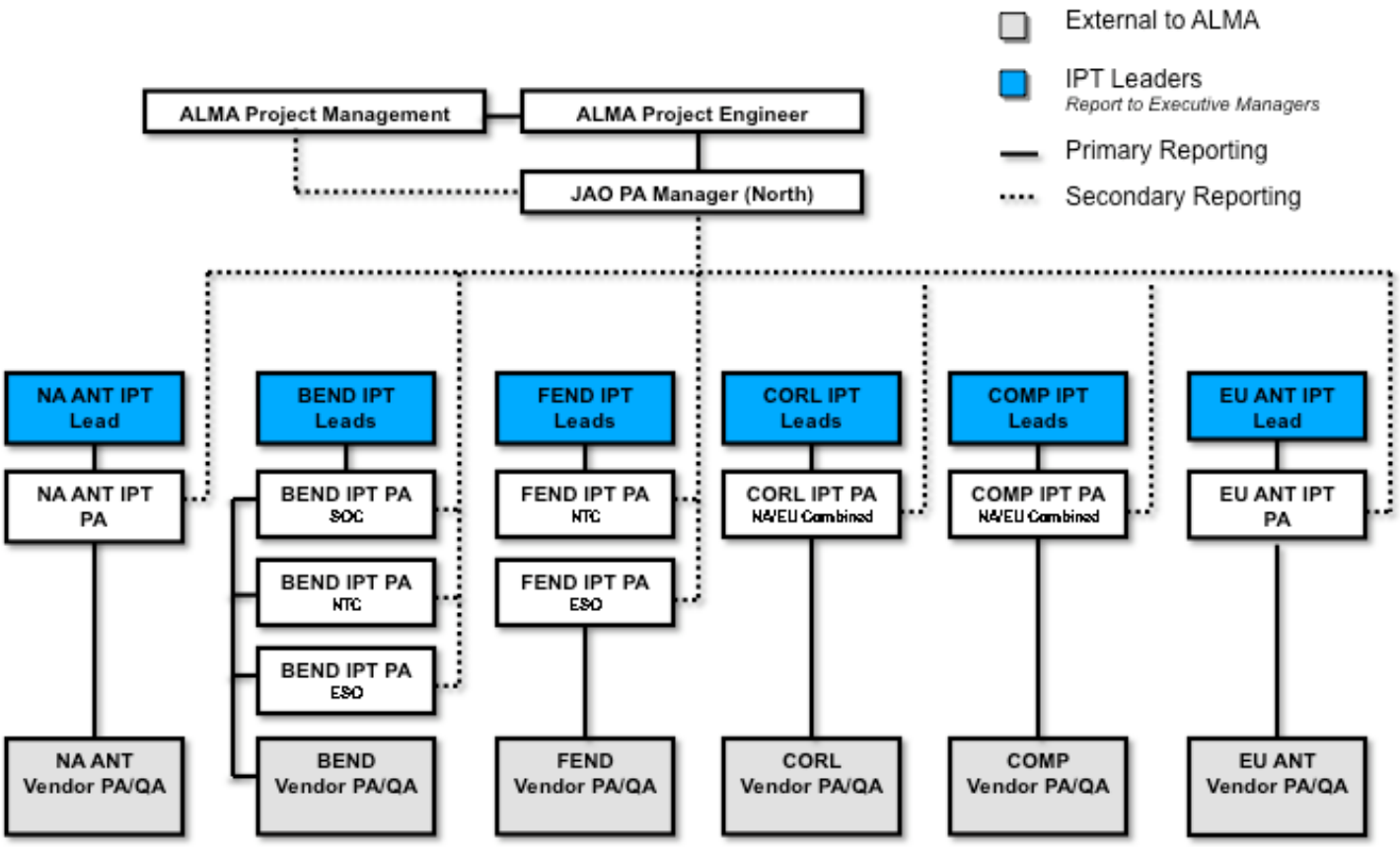

Figure 2: ALMA Product Assurance Organizational Structure – IPT Level Staffing

4.1 Product Assurance Managers

{PA-00010-00/I} The PA managers shall be responsible for the implementation of the PA requirements presented in this document.

{PA-00020-00/I} The JAO PA Manager (North) shall be responsible for:

1. Providing oversight and management for executive PA Leads and interfacing with the IPT PA Principals on PA tasks as shown in figures 1 and 2;
2. Ensuring that a tailored Product Assurance Plan or Quality Manual for each production activity within the IPT groups exists if processes vary from the PA Requirements;
3. Interfacing with the ALMA Project Management and IPT leaders on quality matters in all phases of the project;
4. Verification of the implementation of the PA Plan in the IPT groups;
5. Implementation of the Corrective Action process identified prior to handover to the JAO and the resolution of issues raised during issue analysis;
6. Monitor implementation of acceptance events resulting in the handover of material from the IPT groups to the JAO. Witnessing hardware inspections and instrument testing as required;
7. Supporting IPT and subcontractor reviews.

{PA-00030-00/I} At least one of the JAO PA Managers shall participate in the CCB and have the opportunity to review all change requests, requests for deviation, and requests for waiver from the requirements contained in this document.

{PA-00040-00/I} DELETED. This requirement was removed during Revision D of this document.

{PA-00050-00/I} The JAO PA Manager (South) shall be responsible for:

1. Oversight and management of PA Principals in South America as shown in figure 1.
2. Management and tracking of corrective actions identified after acceptance and the resolution of issues raised during analysis of corrective actions .
3. Management and tracking of Action Items from PAS events performed at the OSF/AOS.
4. Management and tracking of Action Items from process audits at the OSF/AOS.
5. Coordination of inspections for OSF/AOS facility acceptance, maintenance and rework activities.
6. Coordinate procurement of services required in Chile for lab analysis or inspection activities.
7. Development and maintenance of the Site Quality Manual (for OSF and AOS).

4.2 ALMA Integrated Product Teams

{PA-00060-00/I} ALMA IPT Leads shall identify an individual responsible for PA concerns specific to the IPT and subcontractors, hereafter referred to as, "IPT PA Principal."

{PA-00070-00/I} Each IPT shall adhere to the PA requirements defined in this document.

{PA-00080-00/I} If an IPT or subcontractor wishes exemption from one or more of the requirements defined in this document, they must first request permission by submitting a Request for Waiver with justification to the ALMA PA manager and the approval must be referenced in the tailored IPT PA Plan.

Request for Waivers (RFWs) require approval from the ALMA Configuration Control Board (CCB) and the ALMA Project Manager.

4.3 Facility Access

{PA-00090-00/I} The JAO PA managers and designated representative(s) shall have access to all in-house facilities of consortium members, with at least two weeks advance notice, and as defined in the related SOW or contract, required for production activities performed for ALMA project.

{PA-000100-00/I} It is the responsibility of each organization, vendor or subcontractor delivering the ALMA equipment to ensure designated ALMA PA personnel have access to the appropriate areas in their facilities as outlined on the related SOW or contract.

4.4 Planning and Reporting

{PA-00110-00/I} PA updates shall be included as an agenda item in all IPT and subcontractor project progress reports and status meetings to ensure PA requirements remain in consideration throughout the project.

4.5 Procurement Controls

The requirements in this section apply to the purchase orders and contracts prepared for an ALMA IPT by the coordinated effort of the design engineers, PA principal and purchasing groups within a consortium organization. For those top-level procurements that are established by a Memorandum of Understanding (MOU) or Statement of Work and not by a contract, the requirements of this section shall be met as part of the Pre-Production Review (Section 7.1.3). In cases of conflict between this document and Executive procurement rules, the existing Executive rules will have precedence.

{PA-00120-00/I} The IPT PA Principal shall participate in the preparation of material, component, process or manufacturing specifications in close cooperation with design and test engineers.

{PA-00130-00/I} The IPT PA Principal shall review all purchase orders and contracts that procure ALMA configuration items to ensure that applicable PA requirements are included in purchase orders and contracts for deliverable equipment, both hardware and software.

{PA-00140-00/I} The IPT PA Principal shall ensure that all contracts issued for custom engineered products require the submission for approval of a verification plan which details how each of the contractual requirements shall be verified.

{PA-00150-00/I} The IPT PA Principal shall ensure copies of purchase orders and contracts are kept and available for examination by PA staff at their discretion.

{PA-00160-00/I} The IPT PA Principal shall require their subcontractors and suppliers to submit a PA Plan, QA Plan or Quality Manual for review and approval prior to the signing of a contract or purchase order, unless otherwise stated in contract documentation.

This requirement applies to contracts for the production of equipment delivered for use in the construction of the ALMA system at its final location in Chile.

This requirement also applies to contracts which result in the delivery of specifications used to produce equipment that will be delivered for use in the construction of ALMA system at its final location in Chile.

{PA-00170-00/I} When commercial-off-the-shelf (COTS) equipment or components are purchased, a product data sheet from the desired manufacturer shall be supplied with the purchase request including identification of the critical performance specifications.

It is recommended that the quality standard(s) of the component/equipment manufacturer are reviewed by the IPT PA Principal prior to the purchase of any equipment.

5 PROJECT DOCUMENTATION

{PA-00180-00/I} Approval, release and revision of ALMA Board level, Project level and IPT level documentation shall be performed following the procedures defined in Documentation Control Plan, (ALMA-80.02.00.00-011-A-PRO). Figure 3 provides an overview of the ALMA Change Management Process as described in the plan.

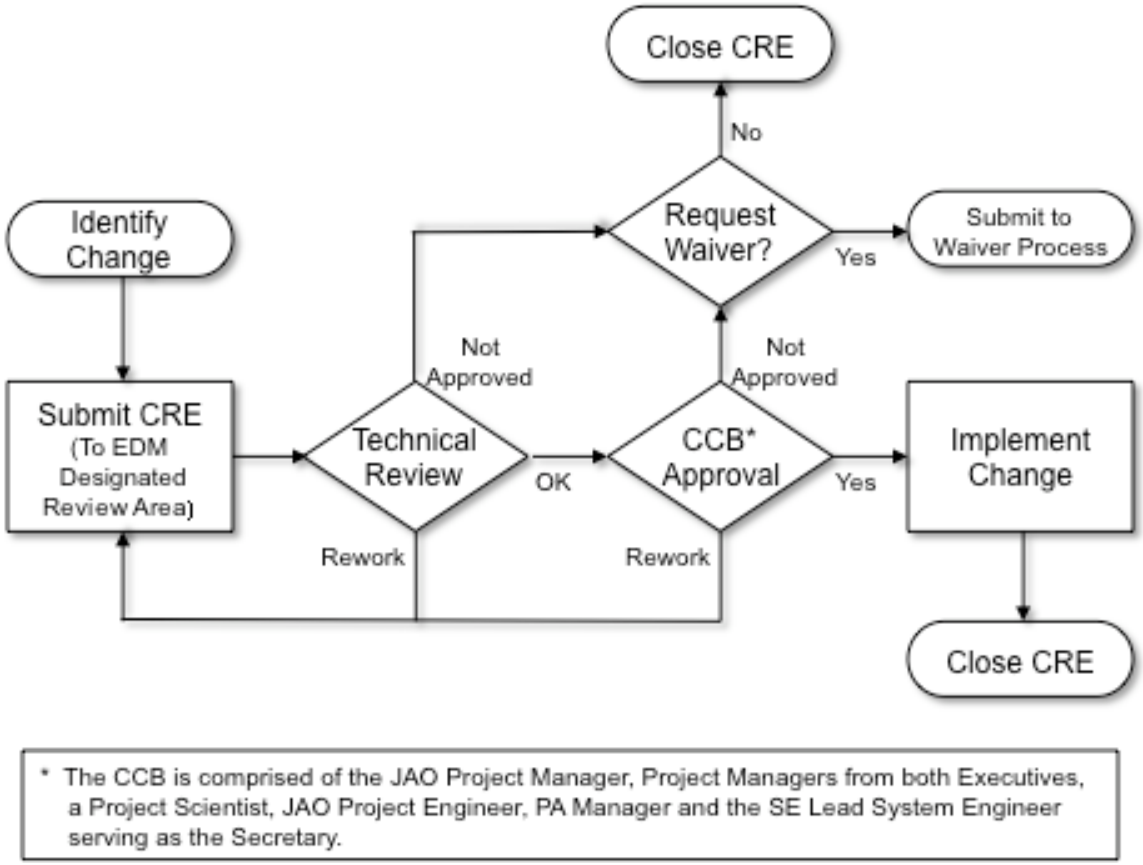

Figure 3: ALMA Change Management Process Overview

6 CONFIGURATION ITEM MANAGEMENT

The following subsections outline requirements associated with the management of configuration items (CIs). Figure 4 provides an overview of the basic process for Configuration Management as defined in the Documentation Control Plan.

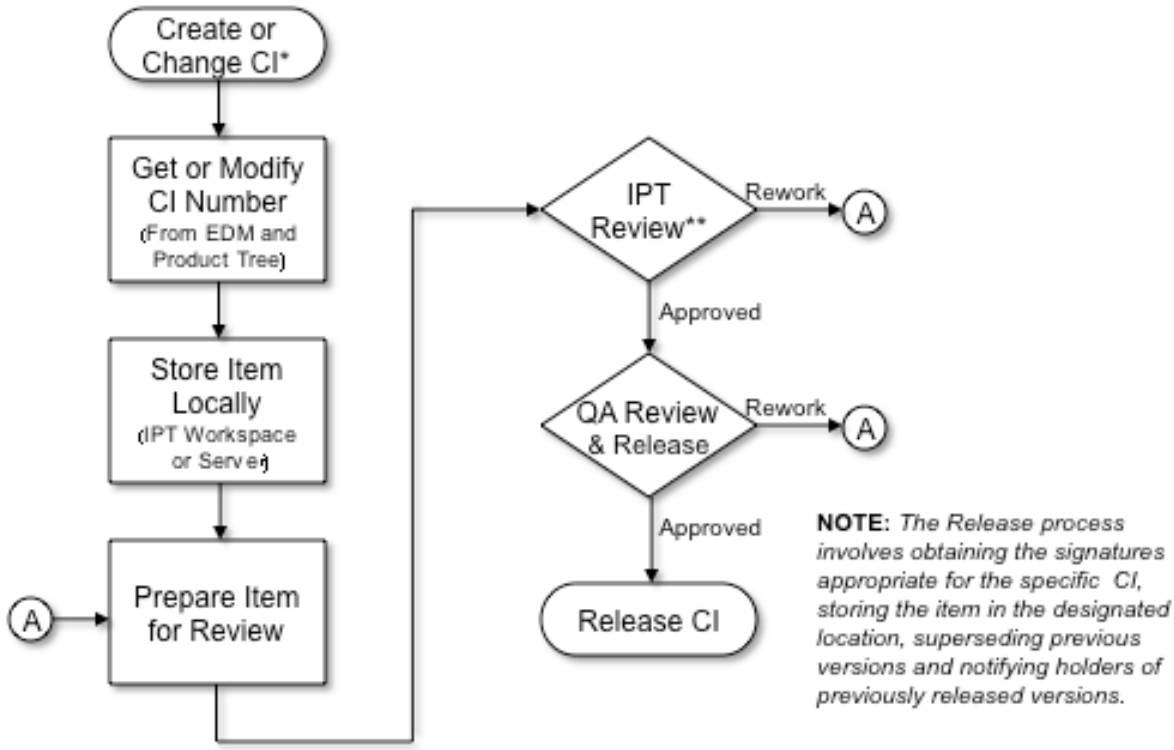

Figure 4: ALMA Configuration Management Process Overview

6.1 Configuration Item Identification

{PA-00190-00/I} Each IPT shall submit a list of their Configuration Items to the review panel and/or acceptance team for review prior to final acceptance in the form of a controlled and released Configuration Item Data List (CIDL). Configuration Items are all work products that are intended to be handed over to the observatory including, but not limited to all documentation, hardware and software. All requests for changes or waivers against this baseline configuration shall also be listed.

{PA-00200-00/I} The PA Principals shall be responsible for compiling and maintaining a comprehensive list of Configuration Items from their groups for all components delivered to Chile for final use on observatory operations.

{PA-00210-00/I} The PA Principal for the group or IPT delivering equipment shall deliver the CIDL to the ALMA Supply Chain Management Group, for entry into the ALMA Inventory Management System.

{PA-00220-00/I} The ALMA Supply Chain Management Group will coordinate with the Operations CMMS group to determine the desired storage and format requirements necessary to transfer data from Construction to Operations.

6.2 Configuration Item Marking

{PA-00230-00/I} The marking and labeling of deliverable hardware and software shall be implemented as defined in Requirements and Guidelines for Identification and Labeling of ALMA Equipment (ALMA-80.02.00.00-016-A-SPE).

{PA-00240-00/I} Each configuration item shall be uniquely identified by serial number.

{PA-00250-00/I} A serial number shall be permanently affixed to each configuration item using a method appropriate to the item which may be indelible ink, engraving, coded electronically readable chip or a combination of the above or equivalent methods. Serial numbers shall not be hand-written.

6.3 Configuration Item Control

{PA-00260-00/I} After a configuration item (CI) has passed formal verification testing (Section 10.1) or acceptance testing (Section 10.2), the current owner shall be responsible for maintaining the integrity of the CI and the accuracy of the CIDL.

This includes controlling the replacement of any hardware component, modification of marking or installation of any software upgrade or patch and the delivery of an updated CIDL.

{PA-00270-00/I} If a formally accepted configuration item is modified in any way, the accompanying documentation shall be updated to reflect the new configuration and the acceptance tests shall be repeated. If this activity is performed by a vendor or delivering IPT, the responsible IPT shall open a tracking ticket in their area to track progress on the modification. The ticket will remain open until the work is completed and a new CIDL and drawings or affected documentation is updated, released and delivered.

6.4 Configuration Item Documentation

{PA-00280-00/I} Documentation shall accompany each configuration item and shall contain a list of all components (including, if applicable, serial numbers) that comprise the overall item.

{PA-00290-00/I} The accompanying documentation shall maintain a history of all equipment and/or component changes which occurred prior to the current version.

7 ENGINEERING

The quality requirements for engineering are intended to ensure the final product has been designed to achieve a high level of quality in addition to a high level of performance. Quality requirements are nothing more than performance requirements which are measured in terms of reliability, availability, repeatability, usability, safety and maintainability.

7.1 Design and Manufacturing Reviews

Design reviews provide the opportunity for the design engineering organization to benefit from the experience and expertise which exists outside of their organization. This is also an occasion to ensure the design being reviewed is consistent with the designs of other organizations which are creating subsystems, assemblies and/or components that will integrate with the equipment under review. Formal completion or closure of a review is not completed until all issues identified by the review panel are addressed to the satisfaction of the decision making authority as defined in the review plan. The decision making authority has the responsibility to assess each of the recommendations from the panel and determine if and how they will be implemented, and to update the AI or issue reflecting this decision. The process for tracking, reporting and closure of Action Items coming out of a review is detailed in Section 13. Figure 5 outlines the review phases and their relationship, detailed in the following subsections.

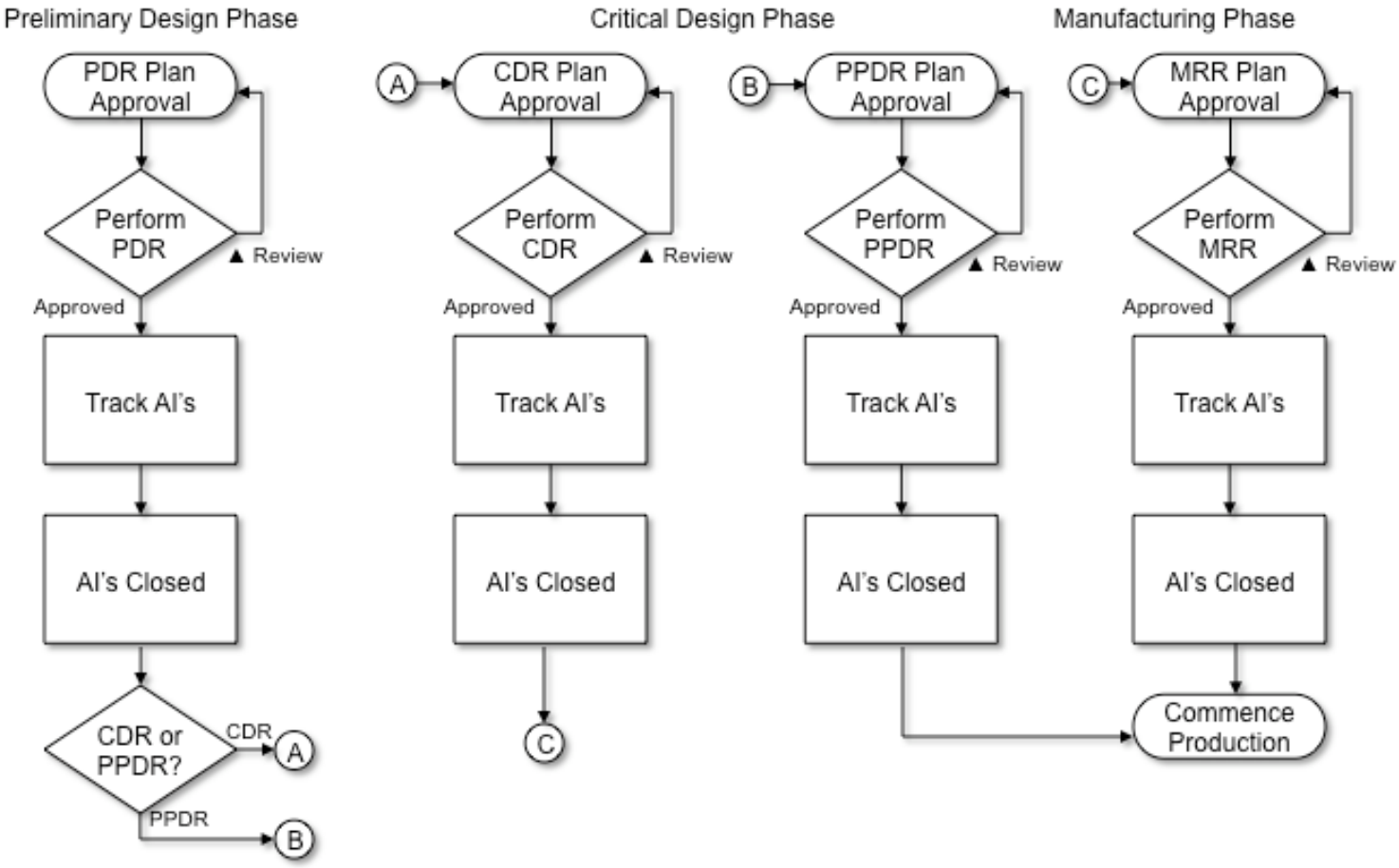

Figure 5: ALMA Design and Manufacturing Review Overview

7.1.1 Preliminary Design Review

{PA-00300-00/I} Product assurance shall be addressed as a review item at each IPT's preliminary design review (PDR).

{PA-00310-00/I} The PDR shall be attended by ALMA PA personnel and the relevant PA documentation shall be prepared and made available for review in advance of the meeting date.

{PA-00320-00/I} Explanation of how ALMA PA requirements are being satisfied shall be provided to ALMA PA personnel during the PDR.

{PA-00330-00/I} The additional requirements and deliverables for the PDR are defined in ALMA Design Reviews Definitions, Guidelines and Procedure, ALMA-80.09.00.00-001-D-PLA. Figure 6 outlines the process defined in this guideline.

7.1.2 Critical Design Review

{PA-00340-00/I} Product assurance shall be addressed as a review item at each IPT's critical design review (CDR).

{PA-00350-00/I} The CDR shall be attended by ALMA PA personnel and the relevant PA documentation shall be prepared and made available for review in advance of the meeting date.

{PA-00360-00/I} Explanation of how ALMA PA requirements are being satisfied shall be provided to ALMA PA personnel during the CDR.

{PA-00370-00/I} Failure modes and their effects shall be assessed during the design and development process and presented as part of each IPT's Critical Design Review.

{PA-00380-00/I} At a minimum, the following points shall be addressed:

- Single point failure modes shall be identified;
- Identification of likely failure modes and the resulting impact on the specific subsystem;
- Critical items shall be identified and listed for review, and
- The failure rates of critical items will be obtained from observed data for similar types of components, if available, or calculated from available data or for similar types of components based on an industry or government accepted analysis methodology.

{PA-00390-00/I} Additional requirements and deliverables for the CDR are defined in ALMA Design Reviews Definitions, Guidelines and Procedure, ALMA-80.09.00.00-001-D-PLA. Figure 6 outlines the process defined in this guideline.

7.1.3 Pre-Production Review

{PA-00400-00/I} A review shall be held prior to the release of any custom (non-commercially available) engineered hardware to an internal or external manufacturing organization to verify that all product and project requirements are satisfied and all critical items have been resolved.

{PA-00410-00/I} At a minimum, the following categories shall be evaluated during this Pre-Production review.

- Product specification completeness including, but not limited to:

- Performance requirements.
- Detailed design compliance with requirements.

- Documentation requirements including, but not limited to:
  - PA/QA procedures;
  - Acceptance test procedures;
  - Manufacturing procedures;
  - Reliability analysis;
  - Maintenance and repair manuals, and
  - Operation manual.

{PA-00420-00/I} Additional requirements and deliverables for the pre-production review are defined in ALMA Design Reviews Definitions, Guidelines and Procedure, ALMA-80.09.00.00-001-D-PLA. Figure 6 outlines the process defined in this guideline.

7.1.4 Manufacturing Readiness Review

{PA-00430-00/I} A review shall be held prior to the start of production or manufacturing of any custom (non-commercially available) engineered hardware by an internal or external manufacturing organization to evaluate the maturity of the manufacturer's documentation and production processes and to highlight areas of risk that need to be monitored during production. Another key component of the MRR is to verify that all critical design issues have been resolved or sufficiently mitigated to the satisfaction of the review panel.

{PA-00440-00/I} Additional requirements and deliverables for the manufacturing readiness review are defined in ALMA Design Reviews Definitions, Guidelines and Procedure, ALMA-80.09.00.00-001-D-PLA. Figure 6 outlines the process defined in this guideline.

7.1.5 Critical Design/Manufacturing Readiness

{PA-00450-00/I} In certain cases, for minor subsystem components, and with the approval of the Project Manager or the Project Engineer the critical design and manufacturing readiness reviews may be combined into a single review. Although the reviews are combined, the deliverable criteria remains the same, but may be tailored to the specific component or subsystem in a JAO approved review plan.

{PA-00460-00/I} Additional requirements and deliverables for the CDMR are defined in ALMA Design Reviews Definitions, Guidelines and Procedure, ALMA-80.09.00.00-001-D-PLA under the CDR and MRR sections of that document. Figure 6 outlines the process defined in this guideline.

7.1.6 Operational Readiness Reviews

For large integration activities and prior to commencement of project level operations, a Project Level review will be held to identify risk areas and assess the processes, planning and resources.

{PA-00470-00/I} For the FE integration centers, a review shall be held to evaluate the design of specialized assembly and test equipment as well as manufacturing capability and maturity of the facility. The requirements and deliverables for the design review of specialized test equipment are defined in ALMA Design Reviews Definitions, Guidelines and Procedure, ALMA-80.09.00.00-001-D-PLA under the CDR section. The requirements and deliverables for evaluation of the facilities manufacturing capability are defined in that same document under the MRR section. Figure 6 outlines the process defined in this guideline.

{PA-00480-00/I} Prior to the start of Early Science and after the Design Qualification Review, a review shall be held to evaluate the size and training of the Operations Team, documentation availability and equipment status and capability.

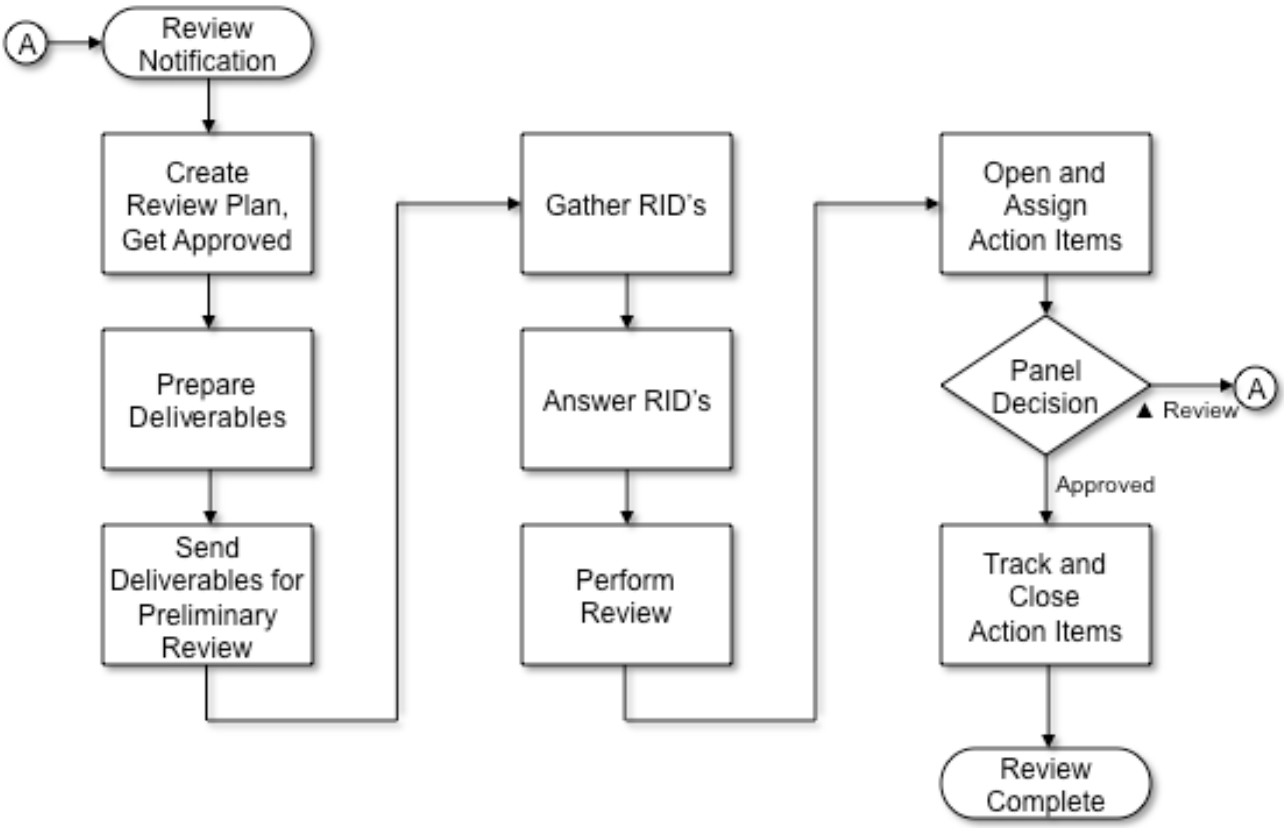

Figure 6: ALMA Review Process

7.2 Design Guidelines

The following list details a series of documents intended to provide consistent and thorough designs across the multiple organizations designing and building various elements of the ALMA instrument. The latest released version of the referenced document available in EDM should be used.

- ALMA Electronic Design Specification and Guidelines, ALMA-80.05.00.00-005-C-SPE
- ALMA System Electromagnetic Compatibility (EMC) Requirements, ALMA-80.05.01.00-001-B-SPE
- ALMA Environmental Specification, ALMA-80.05.02.00-001-B-SPE
- ALMA Interface Management Plan, ALMA-80.07.00.00.001-D-PLA

- ALMA Power Quality Specification, ALMA-80.05.00.00-001-B-SPE
- Standard for Plugs, Socket-outlets, and Couplers, ALMA-80.05.00.00-004-B-STD
- ALMA Design Reviews Definitions, Guidelines and Procedure, ALMA-80.09.00.00-001-D-PLA
- ALMA Guidelines for Identification and Labeling of ALMA Components, ALMA-80.02.00.00-016-A-SPE
- ALMA Safety Risk Analysis procedure, ALMA-10.08.00.00-004-A-GEN
- ALMA General safety design specification, ALMA-10.08.00.00-003-B-SPE

8 RELIABILITY, MAINTAINABILITY, AVAILABILITY

{PA-00490-00/I} All ALMA components and subsystems shall be shown, by demonstration or analysis, to meet the reliability, maintainability and availability requirements as defined in the ALMA Operations Plan, ALMA-00.00.00.00-002-A-PLA. This standard will soon be supplemented by the System Requirements Document.

{PA-00500-00/I} The reliability, maintainability and availability analyses, data and/or test results, also identifying single points of failure, shall be presented for evaluation and approval during the design reviews as described in Section 7 of this document.

9 MANUFACTURING

These requirements are applicable to suppliers or subcontractors that are manufacturing pre-production or production versions of custom engineered equipment to be used in the ALMA system. These requirements do not apply to prototype or proof of concept equipment. The term “batch” as used in this section refers to a group of deliverable components manufactured with the same tools and equipment and having the same baseline configuration.

{PA-00510-00/I} The manufacturer shall submit their production plan, which identifies production steps, batch or lot sizes, processes, assembly stages, key inspection points, and in particular the quality control (inspection and test) stages.

{PA-00520-00/I} Authorized personnel from the ALMA project shall have, at any time and with two weeks notice, unless defined differently in the SOW, access to review all the quality assurance and manufacturing process documentation applicable to ALMA project, and to perform a process audit or site survey as defined in Section 9.1.

{PA-00530-00/I} A batch system shall be set up for production of all custom engineering materials.

{PA-00540-00/I} All pieces in each batch shall be of the exact same configuration.

{PA-00550-00/I} Changes shall be based on approved change requests and can only be adapted for entire batches.

{PA-00560-00/I} Deviations from a batch production method must be defined in an approved production plan.

{PA-00570-00/I} The first piece of each batch shall undergo First Article Acceptance Testing as defined in Section 10.1 and inspected to ensure correct configuration and quality level.

9.1 Process Auditing

{PA-00580-00/I} The IPT PA Principals and JAO Quality engineers, in conjunction with the executive PA Lead and/or the ALMA PA or JAO PA Managers shall evaluate internal and vendor production and manufacturing processes and documentation on a periodic basis to determine compliance with project standards as agreed in a Statement of Work. In some cases, a Process Audit may be referred to as a Site Survey.

{PA-00590-00/I} An Audit Plan shall be developed by the relevant PA Principal describing the standards to which compliance is measured and the process areas that will be evaluated during a specific audit. The recommended Audit Plan Template is ALMA-80.11.00.00-052-A-REP. The Audit Plan shall be forwarded to the IPT Lead, Group Lead or Vendor QA Department prior to scheduling the audit.

{PA-00600-00/I} An Audit Report shall be generated after the Process Audit to identify findings and the resulting action items. The recommended Audit Report Template is ALMA-80.11.00.00-010-A-REP.

{PA-00610-00/I} Action items identified during the audit shall be transferred to JIRA by the PA Principal and updated on a bi-weekly basis.

{PA-00620-00/I} Follow-up audits shall be performed to re-visit the status of previous findings and to evaluate additional process areas not evaluated during the initial audit. The auditing process is outlined in Figure-7 below.

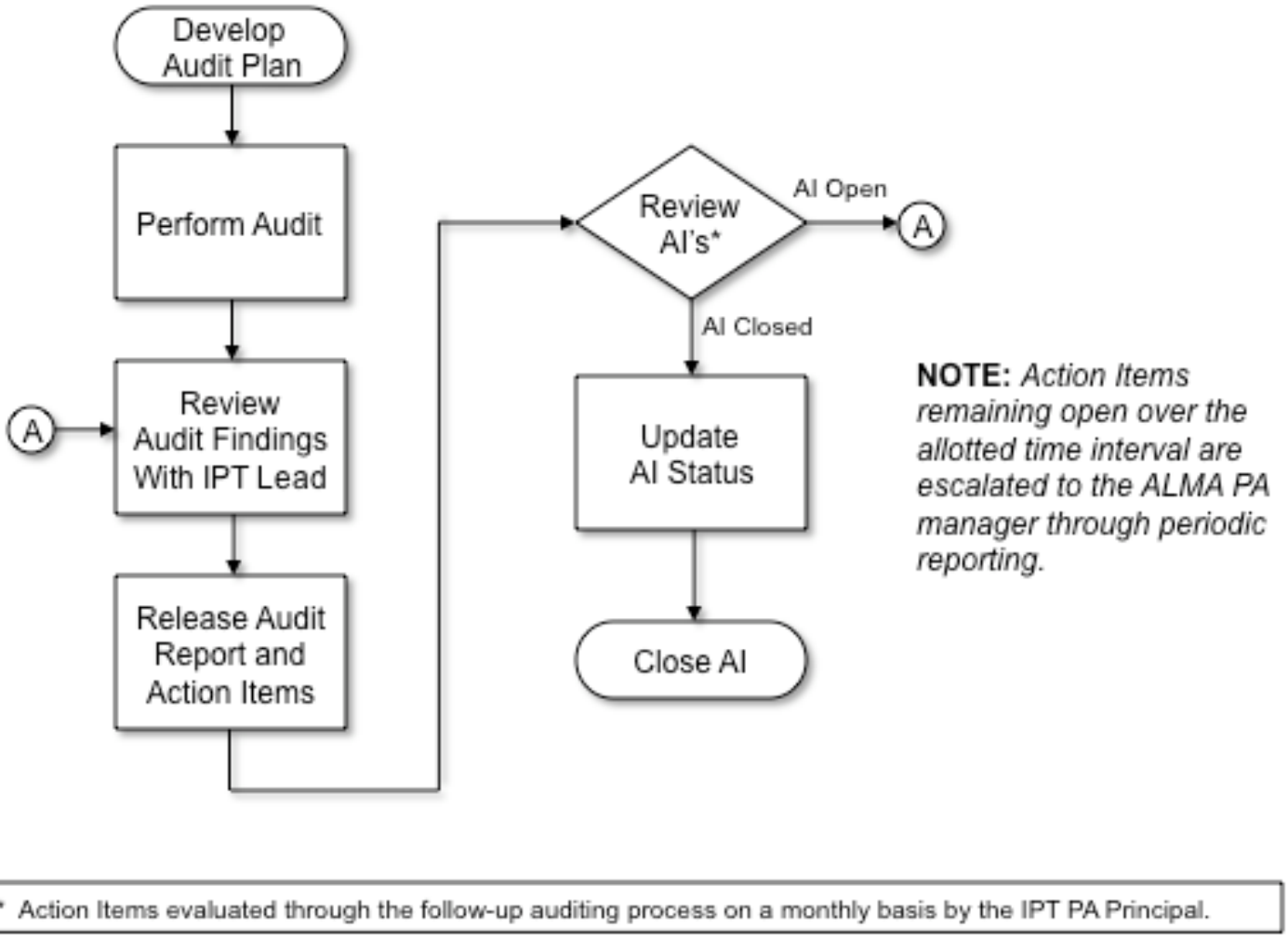

Figure 7: ALMA Auditing Process

10 TEST

10.1 Verification Testing

{PA-00630-00/I} Verification testing shall verify all requirements indentified in the Verification Plan as requiring a “test” as the method for verification.

{PA-00640-00/I} Verification testing shall be performed only on equipment consisting completely of production state components.

{PA-00650-00/I} No prototype components, hardware or software, shall be used in verification testing.

{PA-00660-00/I} Verification testing shall be performed at the facilities of the manufacturing organization or the location of the final assembly of the equipment to be tested.

10.2 Production Acceptance Testing

{PA-00670-00/I} Production acceptance testing shall be performed on each piece of every production batch.

{PA-00680-00/I} Production acceptance testing shall test a subset of the tests performed as part of the verification tests. The composition of this subset of tests shall be defined by the delivering organization in a Verification Plan.

{PA-00690-00/I} No prototype components, hardware or software, shall be used in production acceptance testing.

{PA-00700-00/I} Production acceptance testing shall be performed at the facilities of the manufacturing organization or the location of the final assembly of the equipment to be tested.

10.3 Integration Test

{PA-00710-00/I} Any organization which assembles multiple components or subassemblies received from different suppliers or subcontractors is responsible for generating integration test procedures to verify the integrated device meets all its technical requirements including clear and concise pass/fail criteria.

These test procedures are required to be delivered to the IPT PA principal 30 days prior to the start of the integration testing.

{PA-00720-00/I} The integration test procedures shall describe the following:

- the test environment, test equipment and ALMA equipment required to execute the tests;
- the procedures by which the testing shall be performed;
- the measurements that shall be recorded, and
- the criteria by which the measurements shall be evaluated.

An overview of the testing process is presented in Figure 8 below.

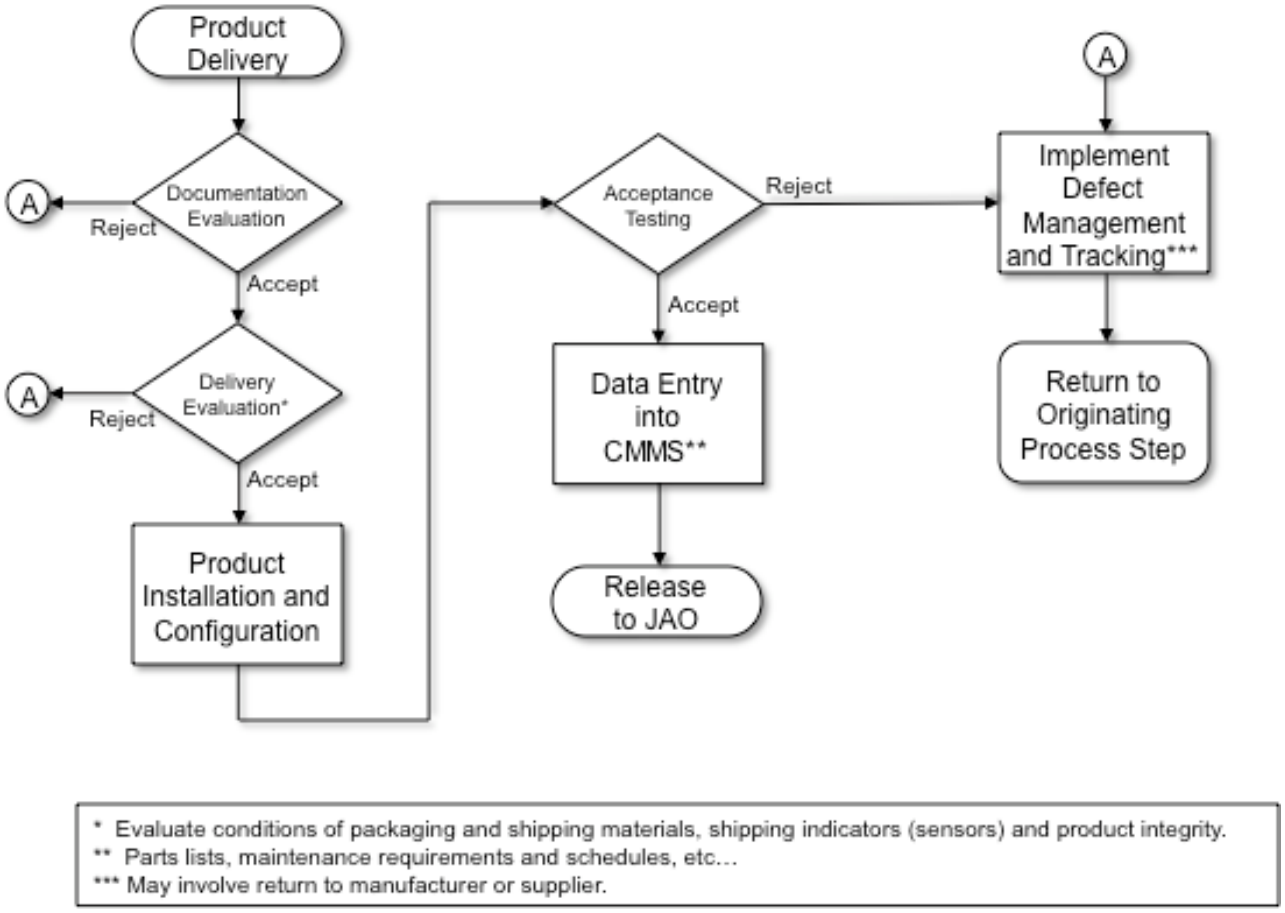

Figure 8: ALMA Testing Process Overview

10.4 Test Witnessing

{PA-00730-00/I} IPT PA personnel or designated representatives shall witness, at a minimum, the first formal acceptance test for all equipment procured from subcontractors

or suppliers which require a formal acceptance test. Witnessing includes verifying that approved procedures are used for testing and data are properly recorded, appropriate personnel participate in the event, a workmanship inspection is performed and issues are captured and included in the acceptance report.

10.5 Test Readiness Review

{PA-00740-00/I} Before the start of formal testing, a test readiness review (TRR) shall be held to verify the test procedures have been approved and the equipment and software under test is in its final deliverable configuration. Additionally, this review will verify that all NCR's, CRE's and RFW's have been approved and that the facilities, resources and test equipment are appropriate for the testing needed and available.

For further clarification, the typical agenda of a TRR is listed here:

1. Review, approval and release of the *Acceptance Test Plan*.
2. Review, approval and release of the *Acceptance Test / Inspection Procedures*
3. Review status of documentation that will need to be delivered for acceptance (CIDL, Drawings, Manuals,
4. Confirmation that the hardware and software are in the final deliverable state.
5. Confirmation that the facilities, equipment and participants are available to begin the acceptance testing.
6. Confirmation that the shipping plan is ready.
7. Confirmation that the safety approval has been received.
8. Review of schedule for testing and delivery activities and preliminary coordination with the customer or receiver of deliverable equipment, software and documentation.

{PA-00750-00/I}The following personnel, at a minimum, shall be invited to participate in the review panel for a TRR: The SE, PA, Safety, representative from the receiving organization or customer (in most cases, this will be AIV).

{PA-00760-00/I}Critical issues identified by the review panel shall be addressed and reviewed prior to the start of formal verification or production testing. The status of minor issues will be reviewed during the acceptance meeting.

10.6 Test Data

{PA-00770-00/I} Test data from verification and acceptance tests shall be recorded in a neat and legible manner on appropriate records. The test data shall include, where possible, prints or plots created directly from the measuring device and shall be provided in electronic format in addition to all original paper records.

{PA-00780-00/I} If the electronic test data is provided via a network server, the external IP network address, full directory path and file name shall be provided without using any virtual machine names or drive letters.

{PA-00790-00/I} All test data submitted for verification or acceptance shall include the printed name and signature of the technician/engineer executing the test and the person witnessing the test as well as the test date and location.

{PA-00800-00/I} All test data, if collected or processed in any way by custom (non-commercial) software, shall include the exact version number of the program and a copy of the executable shall be archived in ALMA EDM.

11 ACCEPTANCE CRITERIA

{PA-00810-00/I} Before custom engineered equipment is shipped to the procuring organization, a Preliminary Acceptance In-house (PAI) event shall be held to examine the following subjects. The event may be a meeting or an organized online, facilitated collection and review of delivered materials.

1. Confirmation that all issues and action items from prior reviews and acceptance events have been closed or have plan to address the issues (proposed solution with due date) approved by management and the acceptance team. This process is further described in Section 13 below.
2. Verification of as-built status and differences from the design specification baseline;
3. Evaluation of test results and inspection results for confirmation of specification and interface requirements;
4. Applicable Non-Conformance Reports (NCRs) and Requests for Waiver (RFWs), Change Requests (CREs) and any open action items from previous reviews;
5. Review of Acceptance Data Package documentation as defined in Section 10;
6. In addition to the above criteria, product material that is delivered to Chile and the JAO shall be subject to additional acceptance criteria and require delivery of additional work products before being accepted by JAO for use in the observatory, as further defined in Section 12.

{PA-00820-00/I} The following personnel, at a minimum, shall be invited to participate on the Acceptance Team for the PAI event: The SE, PA, Safety, representative from the receiving organization or customer (in most cases, this will be AIV). The Project Manager or his delegate is the JAO representative formally authorizing shipment. If delegation is to occur, it will be defined in the event planning documentation.

{PA-00830-00/I} After successful completion of the PAI and approval of the customer, or in the case of work products delivered to the observatory, the Project Manager or delegate, based on an evaluation of the recommendation from the Acceptance Team, the product material shall be shipped to the customer.

{PA-00840-00/I} Upon arrival at the customer location and following the Provisional Acceptance on-Site (PAS) test process and completion of quality records a PAS event shall be held to examine the following subjects:

1. Confirmation that all issues and action items from prior reviews and acceptance events have been closed or have plan to address the issues (proposed solution with due date) approved by management and the acceptance team. This process is further described in Section 13 below.
2. Review the results of incoming inspections;
3. Review the results of performance or basic functional tests to verify that the equipment survived shipment.
4. In addition to the above criteria, product material that is delivered to Chile and the JAO shall be subject to additional acceptance criteria before being accepted by JAO for use in the observatory, as further defined in Section 12.

{PA-00850-00/I} The following personnel, at a minimum, shall be invited to participate on the Acceptance Team for the PAS event: The SE, JAO, PA, Safety, representative from the receiving organization or customer (in most cases, this will be AIV or DTS). The Project Manager or his delegate is the JAO representative formally authorizing acceptance. If delegation is to occur, it will be defined in the event planning documentation.

An overview of the Acceptance Process is provided in Figure 9A below. An elaboration of this process is provided in Figure 9B showing a typical process for preproduction components and Figure 9C shows the condensed or streamlined process for production quality units.

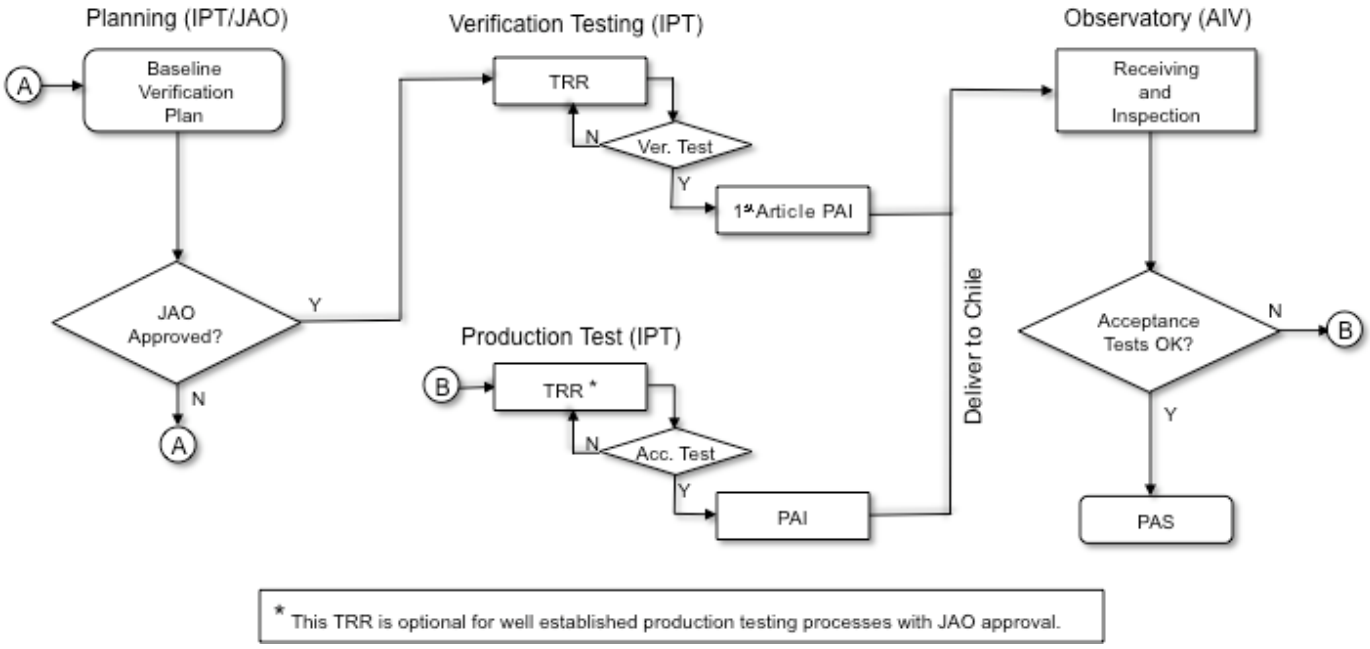

Figure 9A: ALMA Acceptance Process Overview

Figure 9B provides more detail on the activities required to implement TRR, PAI and PAS events for preproduction components. The group responsible for performing each step is indicated in gray text beside each box. The boxes in the blue areas are steps that are optional after the components and processes have reached a mature state, typically when the components progress from pre-production to production. The condensed process without the shaded areas is shown in Figure 9C.

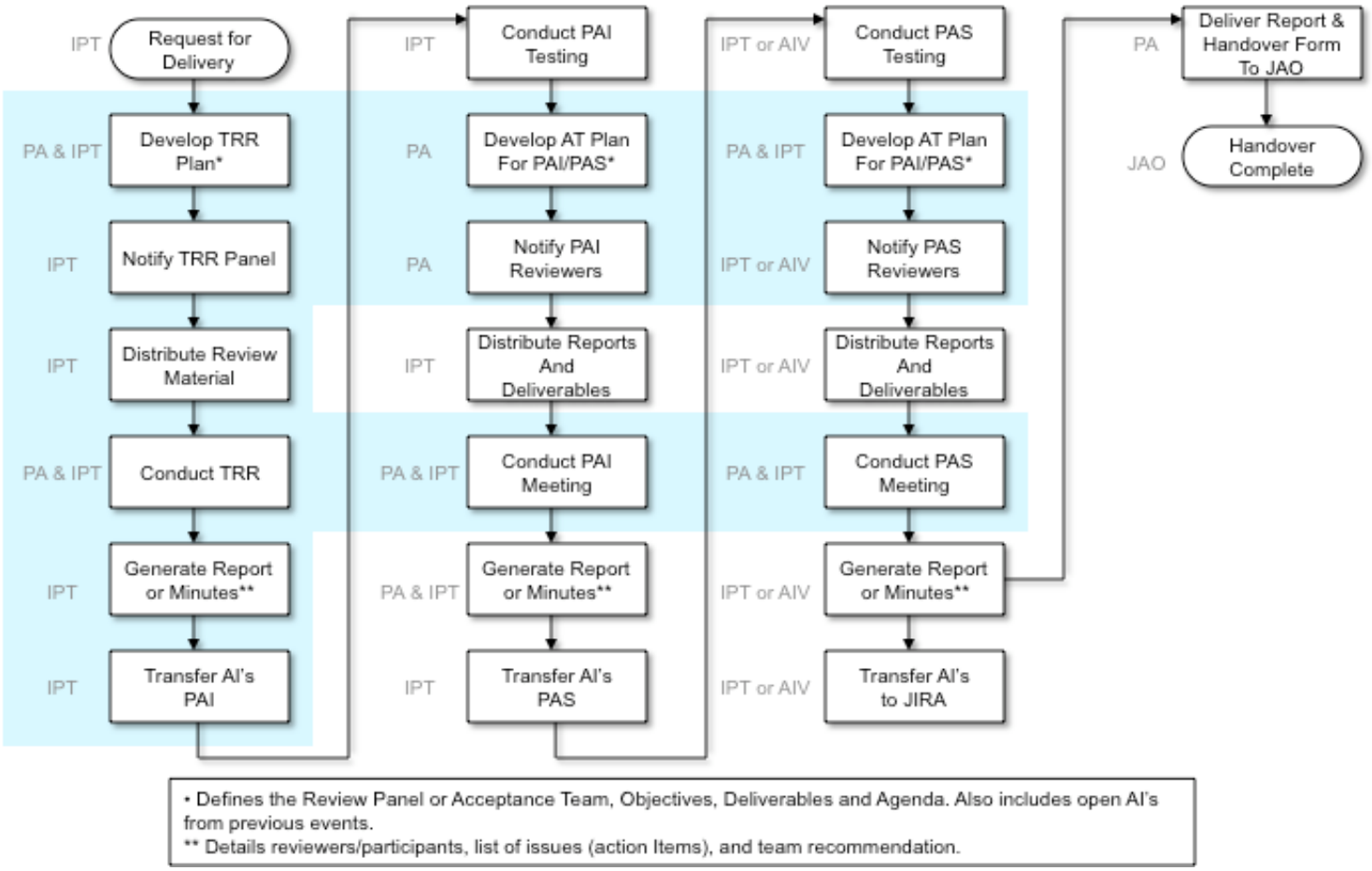

Figure 9B: ALMA Acceptance Process – Details for Pre-Production

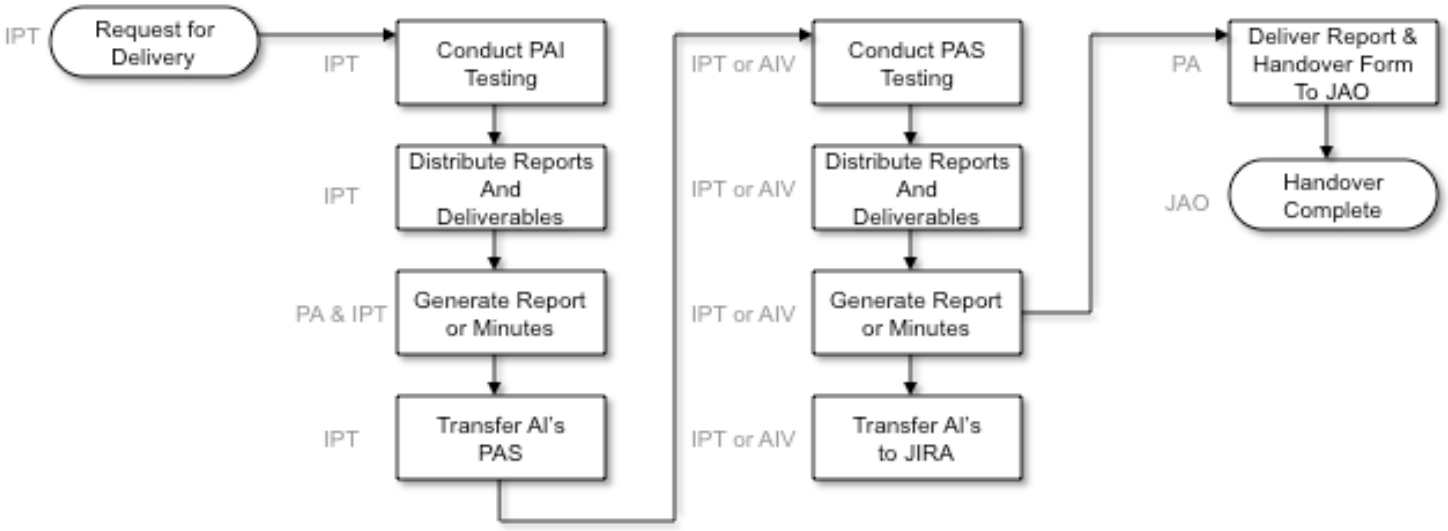

Figure 9C: ALMA Acceptance Process – Details for Production

12 ALMA ACCEPTANCE AND HANDOVER TO THE JAO

{PA-00860-00/I} The documentation supplied in the Acceptance Data Package shall reflect the "as-built" version of the delivered equipment and shall contain sufficient information for the installation, operation and maintenance of this equipment.

{PA-00870-00/I} The IPTs shall require delivery from subcontractors, if applicable, and deliver the documentation identified in the following list, as applicable to the procured equipment. This deliverable documentation shall be referred to in its entirety as the 'Acceptance Data Package.'

1. Configuration Item Data List (CIDL) including a list of CREs and RFWs;
2. Internal and external interface specifications;
3. Verification plans;
4. Acceptance inspection and test reports;
5. Shipping, handling and storage plan;
6. Operation, maintenance and repair manuals, including but not limited to;

- Set-up, operational procedures and normal operating conditions,
- Electrical power specifications including peak starting current, steady-state operating current, maximum allowable voltage fluctuations, and specifications for over-current protection devices,
- Programming instructions for equipment configuration, operation, test and adjustment including description of required external equipment (i.e. laptop, cables, etc),
- Frequency of inspection,
- Frequency and method of functional testing,
- Procedures for the adjustment, maintenance and repair of all elements with additional detail for protective devices and circuits,
- Recommended spare parts list;

7. Safety Data Package, to include but not limited to:
   - Safety procedures, if not described in the operator manual;
   - Declaration of Conformance;
   - Hazard Analysis in accordance with ALMA-10.08.00.00-004-A-GEN, ALMA Safety Risk Analysis Procedures
8. Hardware Documentation;

   Arrangement drawings: Documents the relationship of the major subsystems or components of the system and illustrates assembly placement, cable interconnections, connector identifiers and cabling labels.

   Assembly drawings: Documents the relationship of a combination of parts and subassemblies required to form the next higher indenture level of equipment or system.

   Connection drawings: Documents the electrical connections of an installation or of its component devices or parts.

   Construction drawings: Documents the design of buildings or structures.

   Control Loop Diagrams: Documents the design of all servo systems identifying all components, summing points and signal paths and includes open-loop gain curves, closed-loop gain curves and phase response curves.

   Elevation drawings: Documents vertical projection of buildings and structures or profiles of equipment.

Installation drawings: Documents general configuration and complete installation information including support structure elements such as physical supports, cable trays and routing ducts.

Logic diagrams: Documents, by means of graphic symbols or notations, the sequence and functions of logic circuitry and flows of sequences for operations, maintenance, test and repair. The logic devices should be illustrated using the device manufacturer's symbols if available.

Models, simulations or design databases: Provides a physical, analytical or digital representation of any of the items listed above.

Numerical control drawings: Documents complete design and functional engineering and product requirements of an item to facilitate production by tape control means.

Parts list: Documents each item in the equipment that is individually replaceable and shall include: Item description, type designation, primary and alternate supply sources, general characteristics sufficient to determine replacement item and quantity.

Piping diagrams: Documents the interconnection of components by piping, tubing or hose; the sequential flow of hydraulic fluids or pneumatic air in the system, and all cross-sectional dimensions.

Product drawings: An engineering drawing that documents configuration and configuration limitations, performance and test requirements, weight and space requirements, access clearances, pipe and cable attachments, support requirements, etc. to the extend necessary that an time may be developed or procured on the commercial market to meet the stated requirements.

Schematic diagrams: Documents, by means of graphical symbols, the electrical connections and functions of a specific arrangement. These diagrams shall include names/labels of devices and components, jumper positions, signal flow direction, device types, device pin-outs, circuit board names and external interconnection details.

Sub-system Block Diagram: Provides a description of the functional relationships between all major assemblies comprising the complete deliverable equipment and illustrates the signal flow between the major assemblies.

Timing diagrams: Drawings shall be included which describe and detail all signal events which have timing dependencies.

Wire lists: Documents a book-form drawing consisting of tabular data and instructions required to establish wiring connections within or between items.

Wiring and cable harness drawings: documents the path of a group of wires laced together in a specific configuration so formed to simplify installation. These drawings shall include connector types, connector signal pin-outs, connector names/labels, signal and cable names/labels, cross-sectional dimensions and wiring color codes.

9. Software Documentation;

   Software design documentation: Documents the software items architecture, design requirements, implementation logic and data structures that provide a means of support.

   Software source code listings: Documents the actual source code instructions that represented the "as-built" implementation.

10. Human Documentation;

    Manpower, personnel and training documentation: Document the knowledge, skills and abilities; training requirements; and availability of the humans who operate, maintain and support the system throughout its life cycle.

{PA-00880-00/I} After review by the PAS Acceptance Team as defined in Section 11, and delivery of the Acceptance Team Report containing the recommendation of the team and a list of action items, the ALMA Handover Form (Template Number: ALMA-80.11.00.00-031-A-GEN) shall be created by or delivered to the Project Manager or delegate along with the PAS report.

The Project Manager or delegate, after review and approval will deliver the report and form to the JAO Director. Once the form is signed by the Director, the product material is accepted by JAO for use in the observatory.

13 ACTION ITEM TRACKING, REPORTING AND CLOSURE

{PA-00890-00/I} All issues identified during Project Level reviews (PDR, CDR, PPDR, MRR, CDMR, ORR) and acceptance events (TRR, PAI, PAS, ACRV) shall be formally tracked to ensure issues are addressed by the recommended due dates. Addressing an issue includes closing the items, management or IPT rejection of the issue by delivery and approval of a CRE or RFW, or by having plan to address the issues (proposed solution with due date) approved by management and the issuer.

PA-00900-00/I} Action items from reviews and acceptance events shall be transferred to the project's consolidated issue management tool and shall include an assignee and due date. The IPT PA Principal is responsible for entering and maintaining the status of all action items.

PA-00910-00/I} ALMA PA shall report the status of all action items to the ALMA Project Manager on a bi-weekly basis. The tracking and reporting process is detailed in Figures 10 and 11 below.

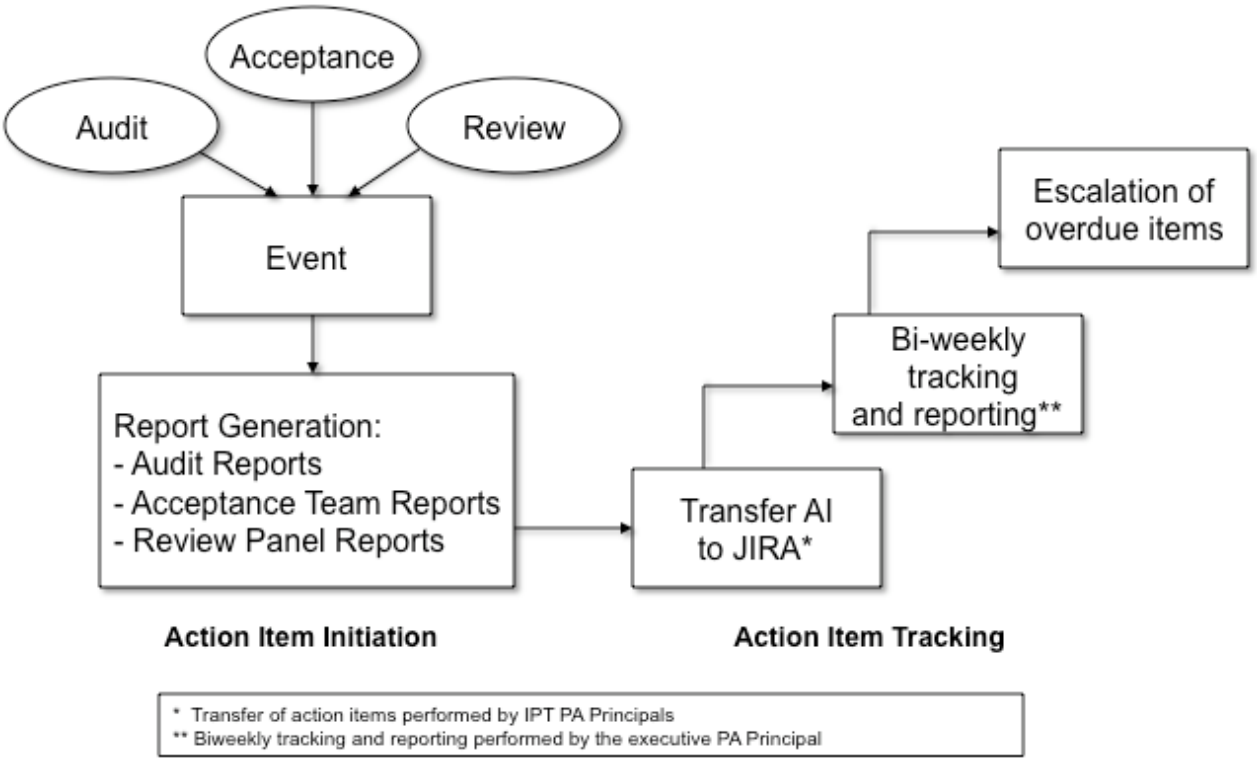

Figure 10: Action Item Lifecycle Overview

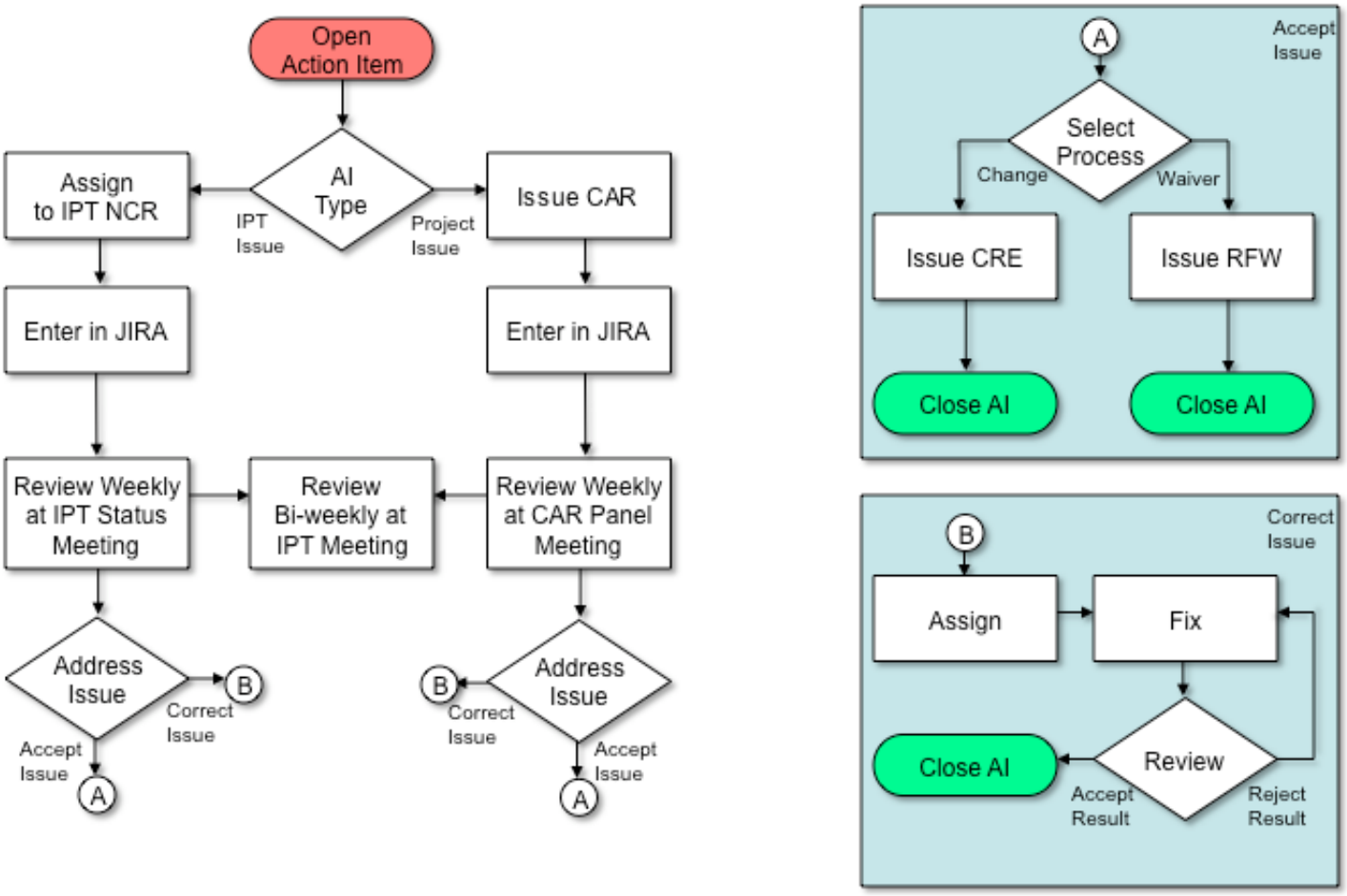

Figure 11: Action Item Tracking, Reporting and Closure Process Detail

14 METROLOGY AND CALIBRATION

The ALMA telescope has many aspects that are unique and require measurement techniques that exceed the capabilities of commercially available measurement equipment. Thus it is impossible to require standard calibration requirements in these situations.

However, the need to ensure accurate and repeatable measurements of these unique performance specifications remains and must be satisfied to the greatest extent possible. Accuracy in an absolute sense cannot be guaranteed but accuracy in the sense of precision and consistency should be achievable.

Hence, the requirements for metrology and calibration are defined below for each of these two situations.

14.1 Commercial Measurement Equipment

{PA-00920-00/I} All commercially purchased test and measurement equipment used in the execution of formal acceptance testing shall satisfy the requirements for metrology and calibration specified in Table 4.

Test equipment that is used as part of the formal acceptance test configuration but is not used to perform measurements shall be clearly marked with the following text: “For Indication Only.”

A calibration plan for all test and measurement equipment which require periodic calibration.
Calibration and control system shall conform to government or industry standards.
Historical calibration records shall be maintained.
All tools and test equipment shall be labeled showing evidence of calibration status.
All test and measurement equipment shall be calibrated by a government or industry certified calibration lab.

Table 4: Metrology and Calibration Requirements

14.2 ALMA-Unique Test Equipment and Measurements

The following requirements are intended to ensure that the measurements of specifications unique to the ALMA telescope are precise and repeatable.

{PA-00930-00/I}The technique(s) used to verify ALMA specifications which are performed using non-commercial test equipment shall be documented and included as part of the test procedures defining this measurement.

{PA-00940-00/I}The test procedures shall also include a description of the theory behind the measurement technique, the exact test configuration, the performance specifications of the equipment used and the exact model and serial number of all equipment used to perform the measurement.

15 SOFTWARE

{PA-00950-00/I} Formal product assurance shall be carried out on all software that is required for telescope observations or supporting operations equipment with the exception of commercial off the shelf (COTS) software.

PA requirements are not applicable to software developed for temporary purposes such as test stubs or demonstration.

{PA-00960-00/I} The requirements listed below refer only to deliverable software unless otherwise stated.

- Software requirements and specification documents shall be maintained on the above software.
- Software verification shall be carried out including reviews and formal acceptance testing.
- Configuration control shall be carried out on software delivered to the ALMA project or software which forms part of other delivered hardware.
- All software media shall be labeled.
- Adequate documentation will be provided with deliverable software to allow the ALMA project to accept, use and maintain the software.

16 SHIPPING, HANDLING AND STORAGE

Shipping guidelines shall be generated to govern the transport of all ALMA components delivered by a supplier or subcontractor. Careful consideration should be given to where deliveries from suppliers and subcontractors are sent for integration, testing and/or final assembly to minimize the number of times equipment is shipped. The intent is to reduce the number of opportunities for damage and help control project costs.

{PA-00970-00/I} Each IPT shall write a shipping and delivery plan for major pieces of hardware; this plan shall identify all the locations that the hardware needs to transit and the required time schedule.

{PA-00980-00/I} This plan shall also address the handling, storage, packaging, marking, labeling and mode of transport requirements for the configuration item(s) being shipped.

{PA-00990-00/I} Handling, storage, packaging and transportation shall be performed such as to prevent damage or degradation of the hardware and software configuration items.

{PA-001000-00/I} When appropriate, the accompanying documentation shall be in the outer packaging layer and shall include the Acceptance Data Package, which includes the storage, handling, transportation, packing/unpacking procedures and relevant notes of caution and safety procedures.

{PA-001010-00/I} All equipment shall be insured for its full value when shipped by commercial carrier unless prohibited by institutional procurement policies.

{PA-001020-00/I} Labeling of shipment containers shall include:

1. nomenclature, model name and serial number (if applicable) of the item;
2. caution/warning notes for dangerous or toxic contents;
3. package orientation arrows;
4. for large items, weight and centre of gravity, handling and lifting points;
5. conditions and instructions for handling and unpacking, and
6. name, address, phone number of sender and recipient.

{PA-001030-00/I} Labeling of shipment containers shall be permanent and legible and protected against wear.

17 INSPECTION

17.1 Shipping Inspection

Once a product has been accepted, during PAI, by the procuring organization, the supplying organization has the responsibility to ensure all required materials are delivered in a safe and timely manner to the procuring organization.

{PA-001040-00/I} To ensure this is done thoroughly each time, a shipping inspection checklist shall be filled out by the supplying organization.

17.2 Workmanship Inspection

A Workmanship Inspection is implemented prior to receiving work products from a subcontractor or IPT. The inspection is implemented to verify that the components are in general good condition, free of defects and are completely assembled.

{PA-001050-00/I} The IPT PA Principal and/or the executive PA Principal shall perform a Workmanship Inspection prior to the acceptance event authorizing delivery, most typically a PAI event.

{PA-001060-00/I} The PA Principal for the receiving organization, typically the IPT PA Principal in the case of material delivered to an IPT, or the JAO PA Principals for material delivered to Chile, shall perform a Workmanship Inspection prior to the acceptance event authorizing handover to the observatory, typically a PAS or ACRV event. A report shall be generated and the findings from the report shall be transferred to action items and transferred to JIRA for formal tracking.

{PA-001070-00/I} All issues identified during a Workmanship Inspection shall be addressed prior to acceptance or handover. If the issue is not corrected, an agreement shall be made between the delivering and receiving parties to accept the material with a CRE or waiver, or on a plan to correct the issues after delivery. In the latter case, an action item shall be opened to ensure the issue is corrected in the allotted timeframe.

17.3 Incoming Inspection

Incoming inspections are carried out by the organization placing orders or by delegated technical staff. Special attention shall be given to handling, visual inspection and measurements to confirm agreement with purchase order or subcontract.

{PA-001080-00/I} The IPT PA principal shall ensure that the actions listed in Table 5 are performed at incoming inspection of all configuration items.

Materials shall be identified to the applicable purchase order/subcontract upon receipt. The identification tag/stamp shall follow the material until final acceptance.
Materials awaiting inspection or test shall be kept separated from material which has either passed inspection and is accepted or has failed inspection and is waiting to be repaired or returned.
Parts will be inspected for count and condition, part marking, color coding, serial numbers and other required identification marking.
Vendor furnished certificates of compliance or other certifications can be used to determine compliance with purchase order/subcontract specifications only if the vendor's quality control system has been evaluated for effectiveness and integrity.
All compliance documentation shall identify by serial number the specific item the documentation is applicable to.
Non-conforming material shall be identified during the incoming inspection and returned to the Vendor for replacement and/or repair. If the Vendor believes that a flaw is insignificant, he can request a waiver for the error.

Table 5: Incoming Inspection Tasks

17.4 Sampling Plan

{PA-001090-00/I} The incoming inspection described in Section 17.3 shall be accomplished according to the sampling plan given in Table 6 for each of the specified quantities of lot size received. This is performed on bulk material and components, unless these items are determined by the IPT to be a critical item requiring 100% inspection and testing.

Lot Size (pieces)	Sample Size (pieces)	Maximum no. of non-conforming pieces in sample for acceptance of lot	Minimum no. of non-conforming pieces in sample for rejection of entire lot
0 – 90 pieces	Equal to Lot Size	0	1
91 – 150	20	0	1
151 – 280	32	0	1
281 – 500	50	1	2
501 – 1200	80	2	3
1201 – 3200	125	3	4
3201 – 10,000	200	4	5
10,001 – 35,000	315	5	6
35,001 – 150,000	500	6	7

Table 6: Incoming Inspection Sampling Plan

This sampling plan is based on the General Inspection Level II ANSI/ASQC Z1.4-1993 Sampling Procedures and Tables for Inspection by Attributes for an Acceptable Quality Level (AQL) of 1%.

18 SAFETY

{PA-001100-00/I} All personnel shall be alert to the need to identify potential safety hazards. Once identified, steps shall be taken to eliminate them, or reduce them to levels judged acceptable. The central point of contact for safety matters shall be the appropriate IPT safety liaison.

{PA-001110-00/I} Safety assurance matters shall conform to the requirements defined in the ALMA Safety Manual, ALMA-10.08.00.00-001-C-MAN and with site specific Safety directives.

{PA-001120-00/I} Potential hazards shall be identified as a part of the normal design process and eliminated or reduced as far as possible. Safeguards shall be determined for outstanding hazards which will reduce their possible effects to the lowest reasonable level in accordance with the ALMA Safety Risk Analysis Procedures, ALMA-10.08.00.00-004-A-GEN.

{PA-001130-00/I} Any safety hazards that cannot be eliminated during the design process shall be reported to the ALMA Safety Officer principal at the design review and

subsequent progress shall be reported, including necessary proof that the relevant requirements have been satisfied.

A general overview of the ALMA Safety process as defined in ALMA Safety Manual is provided in the figure below.

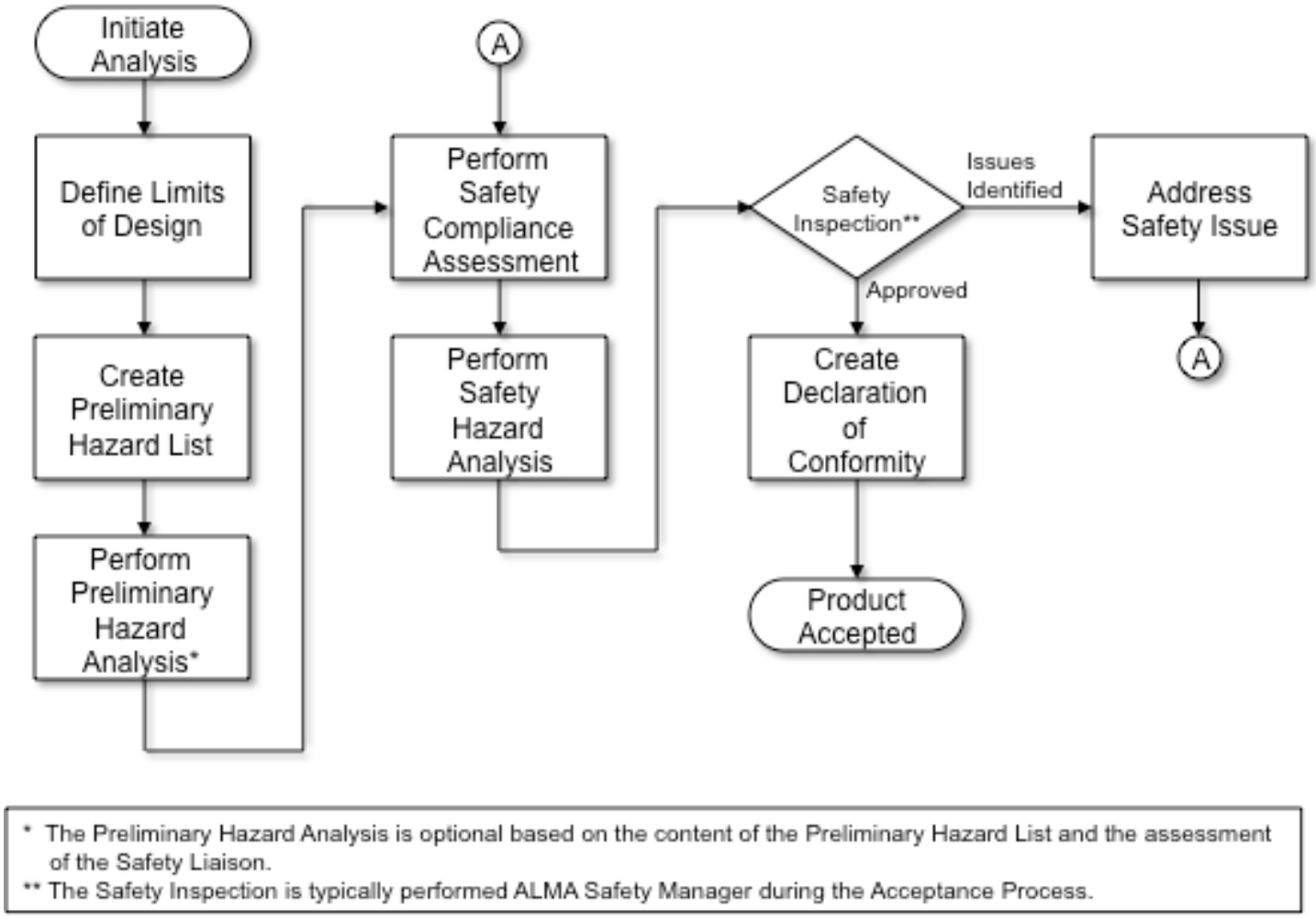

Figure 12: ALMA Safety Process

19 CORRECTIVE ACTION REQUEST PROCESS

The Corrective Action Request (CAR) process provides a procedure to identify potential issues with the project-level configuration and that require changing a project level process, specification, requirement, drawing or ICD, or that may result in a waiver to

accept non-conforming product material or process. A major objective of this process is to examine failures of performance, functionality or fit during system integration and commissioning, to identify which are a result of design flaw, and to correct the documents that define the design. Additionally, it is used to initiate an investigation of issues with unknown causes, resolutions or implications.

The following subsections detail requirements associated with the implementation of a CAR process. Figure 13 provides an overview of the process flow.

19.1 Material Review Board

The Material Review Board (MRB) is a core panel of System Engineering (SE) members, including PA, that shall meet on a weekly basis to review the status of existing CAR's and to address new CAR's. Additional, ad-hoc, MRB sessions may be called by the core panel in order to accelerate actions for urgent issues, or to elicit external expertise from other IPT's and portions of the project.

{PA-001140-00/I} The primary function of the core MRB team will be to:

- Determine if a submitted issue is a project issue or an IPT issue.

- Assign or change the state of an issue.

- Request personnel to investigate or address an issue and recommend due dates. The request becomes an assignment when the respective supervisor agrees to the request. Otherwise the supervisor may delegate the assignment or shall formally reject the request by updating the request with reasons for rejecting and the MRB will forward the matter to the MIPT for resource allocation or acceptance of the issue.

- Close issues and update the lessons learned archive.

{PA-001150-00/I} The Material Review Board shall be comprised of the following core minimum participants, assigned by SE Lead:

- SE Representative(s)

- Engineering Representative(s)

- PA Representative(s)

- AIV Representative(s)

- Department of Technical Services Representative(s)

Additional representatives shall be invited to meetings depending on the content of the issues being reviewed, that may require external input or decision making criteria and may include representatives from Management, the affected IPT and Safety.

19.2 Issue Identification

{PA-001160-00/I} A CAR may be submitted by any member of ALMA construction, ALMA operations, or from any vendor or supplier through their respective ALMA contact. The issuer shall open a JIRA ticket with a description of the issue along with related documentation, pictures and links to existing tickets or NCR's in other IPT areas.

To further clarify the difference between a CAR and an NCR, the following definitions are given:

– A CAR is initiated to investigate a high level issue with unknown cause or responsibility for correction. Once a CAR is processed, it may be downgraded to a NCR.

– A NCR is the method of correcting a known issue with clear cause and method of correction. A non-conformance with unknown cause or a responsibility for correction may be escalated to a CAR.

19.3 MRB Review

{PA-001170-00/I} The MRB shall be responsible for accepting, rejecting, changing the state, and closing a CAR.

{PA-001180-00/I} The MRB may elect to solicit external expertise to analyze the impact and possible solutions of an issue. Management, IPT and PMCS may need to provide input for issues requiring schedule, staffing and budget adjustments.

{PA-001190-00/I} The core MRB panel shall meet on a weekly basis, with ad-hoc meetings and attendees as needed.

19.4 Issue Analysis

{PA-001200-00/I} Each issue will be addressed by the MRB and will be assigned one of the following states and additional information as indicated below and detailed in Figure 13:

New: This is the initial state after a CAR is entered into JIRA and prior to review by the MRB.

Analyze: The CAR is assigned to this state while being reviewed by the panel, or if assigned to an IPT or other ALMA personnel for evaluation. During this phase, responsibility is assigned and due date is added to the CAR, along with a recommended deliverables such as an analysis report or recommendations on how to correct the issue. The respective supervisor of the assignee may delegate the assignment to another person or shall formally reject the request by updating the request with reasons for rejecting and the MRB will forward the matter to the MIPT for resource allocation or acceptance of the issue. An ad-hoc MRB may be scheduled during this phase if external expertise is required for analysis.

Transfer: The first of three possible outcomes of the Analysis phase is that the issue does not affect more than one IPT or that it does not require Project Level intervention. In this case, the CAR is assigned to a specific IPT to be tracked using the IPT's internal NCR process. The CAR will remain open until it is verified that issue is tracked internally within the IPT.

Accept: The second possible outcome of the issue analysis is that of accepting the issue. In order for an issue to be formally accepted, a Change Request (CRE) or a waiver (RFW) shall be initiated. The MRB shall assign a person or group responsible for implementing the CRE or RFW and a due date for the action. The respective supervisor of the assignee may delegate the assignment to another person or shall formally reject the request by updating the request with reasons for rejecting and the MRB will forward the matter to the MIPT for resource allocation .

Fix: The final possible outcome of analysis is that the issue should be corrected. Once the analysis is complete and a solution is agreed upon by the panel, sometimes based on feedback from the IPT and external consultants, the CAR state is set to Fix while the solution is being implemented and the due date is adjusted to reflect the anticipated completion of the fix.

Test: Depending on the nature of the issue and the solution, a verification of implementation may be required. In this case, the CAR state is set to Test until the data are presented to verify that the implementation was successful.

Close: During this final stage of review, the MRB shall verify that all ancillary issues are addressed such as updates to drawings, manuals and other documentation affected by issue correction. Once this is verified, the CAR is closed.

During the analysis process defined above, when assignments for actions identified by the MRB panel are allocated outside of the panel, the assignee will be added to the mailing list for the JIRA ticket and the executive leader will be notified of the requested assignment. The respective supervisor of the assignee may delegate the assignment to another person or shall formally reject the request by updating the request with reasons for rejecting and the MRB will forward the matter to the MIPT for resource allocation.

19.5 Issue Tracking

{PA-001210-00/I} The status of CAR's shall be reported to the Management IPT on a bi-weekly basis by Product Assurance. This reporting event also provides the opportunity to escalate urgent issues.

{PA-001220-00/I} The project goal is to address issues in a timely manner and have set a timeframe of 60 days for closure of issues. If issues are overdue more than 60 days past the due date, then they shall be escalated to the Management IPT.

19.6 CAR Tool

{PA-001230-00/I} The primary tool used for tracking CAR's and reporting status shall be the online JIRA Issue Management system. The tool provides a web-based interface with a central database located in Santiago, Chile.

The CAR location in JIRA is in the "ALMA PA" Category in a project labeled "ALMA Corrective Action Requests and Non-Conformance Reports". Following is a link to the online location:

http://jira.alma.cl/browse/CAR

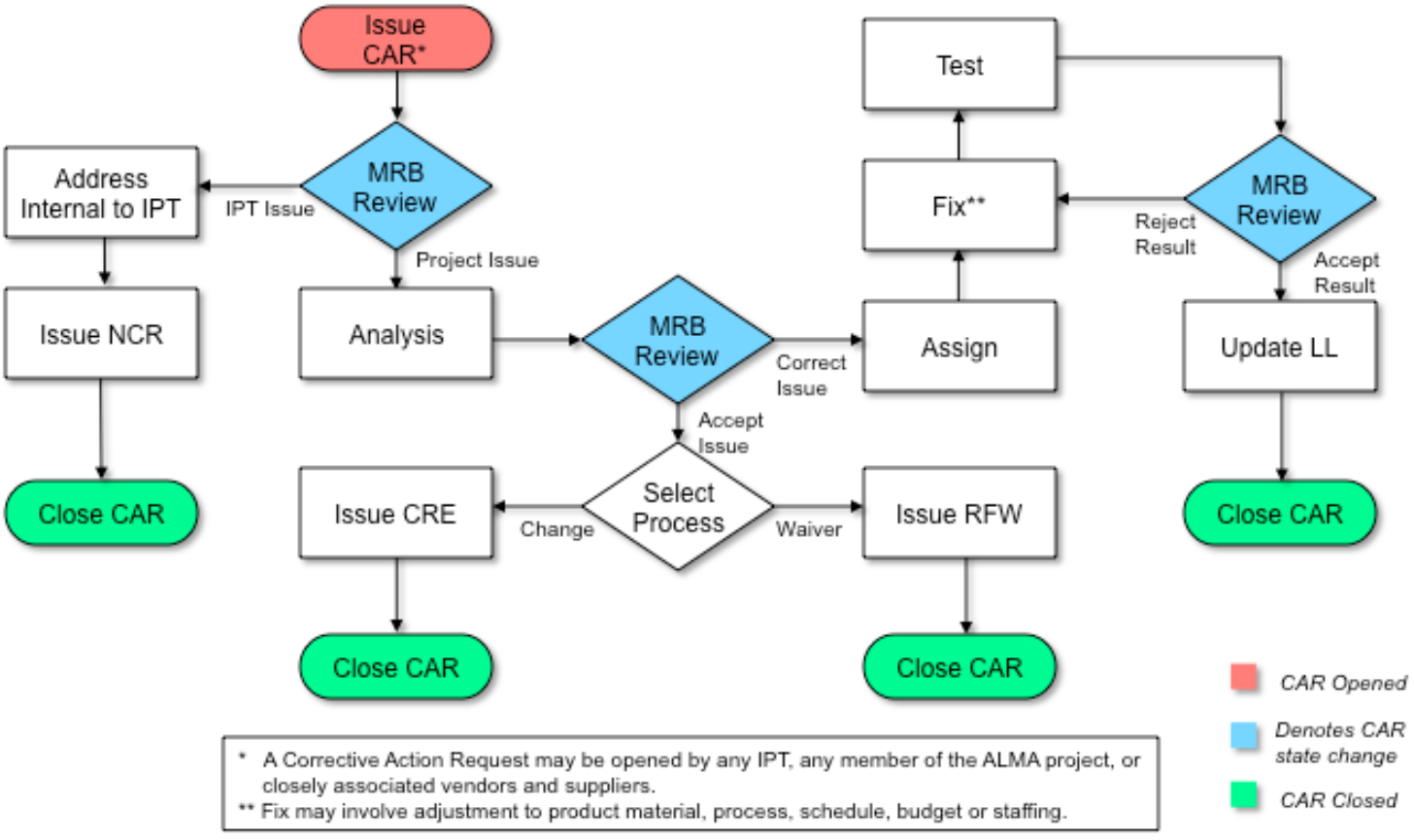

Figure 13: Corrective Action Request (CAR) Process Overview

20 NON-CONFORMANCE REPORTING PROCESS

The Non-Conformance Reporting (NCR) process provides a procedure to identify and track IPT internal issues with product material or processes that do not meet the specification and that may result in a change request to modify requirements, or a waiver to accept non-conforming product material. A major objective of this process is to examine failures of process, performance, functionality or fit during acceptance or inspection of material received from subcontractors, or that is manufactured internally to the IPT.

The following subsections detail requirements associated with the implementation of a NCR process.

{PA-001240-00/I} Each IPT or production group within the IPT manufacturing work products to be delivered to the project shall implement a formal NCR process.

20.1 NCR Identification

{PA-001250-00/I} All product issues identified during the manufacturing and acceptance processes shall be recorded within the NCR tracking system.

{PA-001260-00/I} A NCR shall be generated for each issue identified during the incoming inspection, testing and receiving process. These issues shall be forwarded to the vendor or delivering party with the appropriate vendor required documentation or forms (like an Returned Material Authorization). Such vendor required documentation shall be attached to the NCR in the tracking system.

{PA-001270-00/I} For external vendors, a NCR shall be generated for each issue identified during the acceptance testing and delivery processes. NCR's received from customers or receiving parties shall be entered into the tracking system and any documentation, pictures or issue descriptions shall be attached to the NCR entry.

20.2 NCR Tracking and Closure

{PA-001280-00/I} All NCR's shall be assigned a specific person responsible for addressing the issue (with approval of supervisor), which may include various steps of analysis, implementation and testing. Additionally, a due date shall be assigned to each phase (analysis, correction, testing) of issue management.

{PA-001290-00/I} All open NCR's shall be reviewed by the IPT on a weekly basis to determine the status and required actions. During these reviews, the assignees and due dates will be adjusted as needed.

{PA-001300-00/I} The IPT PA Principal shall review all open NCR's bi-weekly to verify that none are excessively overdue and that actions are being implemented to address the issues.

{PA-001310-00/I} Once the IPT determines that an issue is properly implemented, or assigned a CRE or RFW as appropriate, the issue status shall be set to Resolved.

{PA-001320-00/I} After review of the implemented solution to ensure that all reviews and approvals have been implemented, and that all ancillary documentation affected by the issue has been updated, the PA Principal shall set the issue status to Closed.

20.3 NCR Reporting

{PA-001330-00/I} The IPT PA Principal shall, on a bi-weekly basis, ensure that the current status is properly reflected in the tracking tool.

{PA-001340-00/I} Executive PA Principals and PA Leads shall report overdue issues to IPT Management and ALMA PA on a biweekly basis.

{PA-001350-00/I} ALMA PA shall report the status of all overdue NCR's to ALMA Management on a bi-weekly basis.

{PA-001360-00/I} A comprehensive list of all NCR's shall be delivered in the documentation package, typically as an attachment or addendum to the CIDL during PAI and PAS events.

20.4 NCR Tool

{PA-001370-00/I} The recommended tool for tracking NCR's and reporting status is the online JIRA Issue Management system. The tool provides a web-based interface with a central database located in Santiago, Chile. The tool interface allows the creation of component based categorization and tracking of issues, email notifications and streamlined report generation.

21 RISK MANAGEMENT PROCESS

The ALMA Risk Management process is defined by Management in the ALMA Project Plan and intended to identify, escalate and track project risk and to ensure the development of mitigation plans and the enactment of contingencies prior to realization.

{PA-001380-00/I} The IPT PA Principals, Executive PA Principals, ALMA PA Manager and the JAO PA Manager shall notify management of all risks identified during reviews, acceptance events, process audits and product inspections.

The ALMA Risk Management process, as defined in the ALMA Project Plan is detailed in Figure 14 Below.

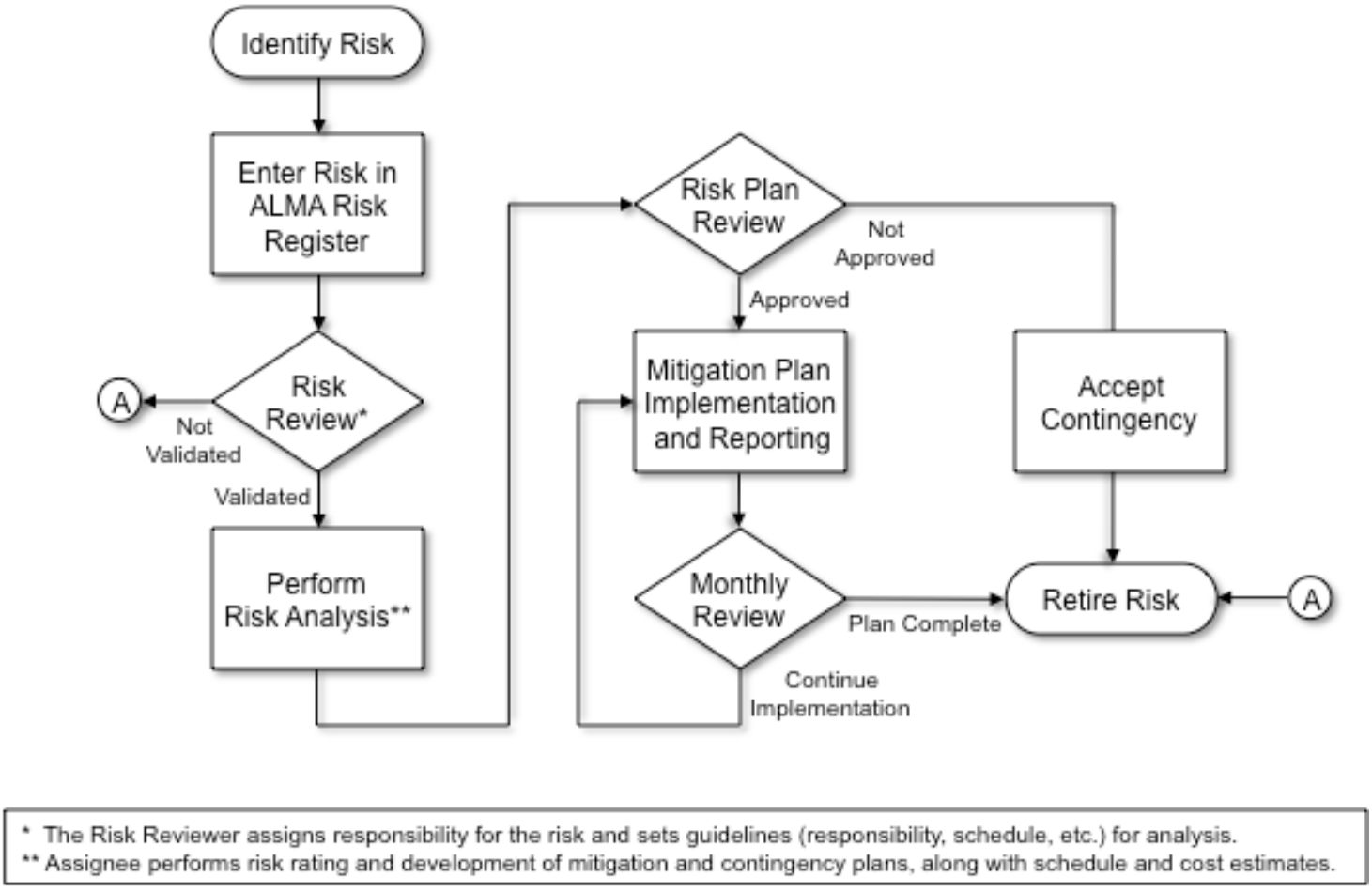

Figure 14: ALMA Risk Management Process

22 SCHEDULING PROCESS

The event scheduling process is designed to formally reserve project time and resources necessary to conduct formal project level reviews, acceptance events and warranty work. and to enhance the accuracy of the IPS. The following subsections describe the steps necessary to effectively implement the event scheduling process and a process overview is provided in Figure 15.

22.1 Requesting an Event

{PA-001390-00/I} In an effort to procure the necessary resources required to conduct a project level review or acceptance event, the IPT or delivering party shall initiate the request process by making an entry into the project's event request tool, to alert the appropriate stakeholders and decision makers. The area is located here: http://www.jira.cl/browse/SCHEDULE

{PA-001400-00/I} The following information shall be provided in the event request:

- Recommended Facilitator or Chairman. If none is requested, the IPT PA Principal will by default be selected as the event leader, or the JAO will recommended a leader meeting the required criteria for the type and level of event.
- Recommended Acceptance Team or Review Panel members. If none are provided, the ALMA PA or the JAO will recommend qualified personnel based on the event requirements as defined in the ALMA Review Guidelines.
- Required timeframe for the event, the tolerance in days around the target date and the criticality of meeting the target. Providing a reference of linked dependencies is highly recommended.
- Desired duration and location of the event and a recommendation for external connectivity (audio and/or video).

22.2 Confirming Stakeholder Participation

{PA-001410-00/I} The IPT PA Principal, or designee, shall add all referenced or involved personnel (participants) to the email list in the event request tool and obtain tentative commitments from participants, or find delegates in the event of primary designee unavailability.

22.3 PMCS Scheduling Management

{PA-001420-00/I} Once participation is tentatively confirmed, the IPT PA Principal shall notify the PMCS Group of the preferred event date and duration.

{PA-001430-00/I} If the desired date is available (no conflicts exist with previously scheduled events), the PMCS Group shall add or update the IPS with the approved date.

If the date is not available, the IPT PA Principal shall negotiate a new date with the PMCS Group and the IPT Managers.

{PA-001440-00/I} Once the event date is confirmed, the IPT PA Principal shall notify the event chairman or leader to proceed with distribution of the review or acceptance plan and associated data package.

22.4 Re-scheduling an Event

{PA-001450-00/I} If for any reason the event can not be conducted as planned, and as defined in the ALMA Review Guidelines (data package not available by the due date, reviewers become unavailable or participation is unacceptable), the IPT or delivering party shall start the scheduling process again by submitting a request to postpone or reschedule the event.

{PA-001460-00/I} If the requested new date is available, the Review or Acceptance Plan shall be updated and redistributed and the PMCS Group shall modify the IPS accordingly.

{PA-001470-00/I} If the requested new date is not available due to a conflicting event, the IPT PA Principal shall negotiate with the PMCS Group and the IPT Managers to agree on a new date.

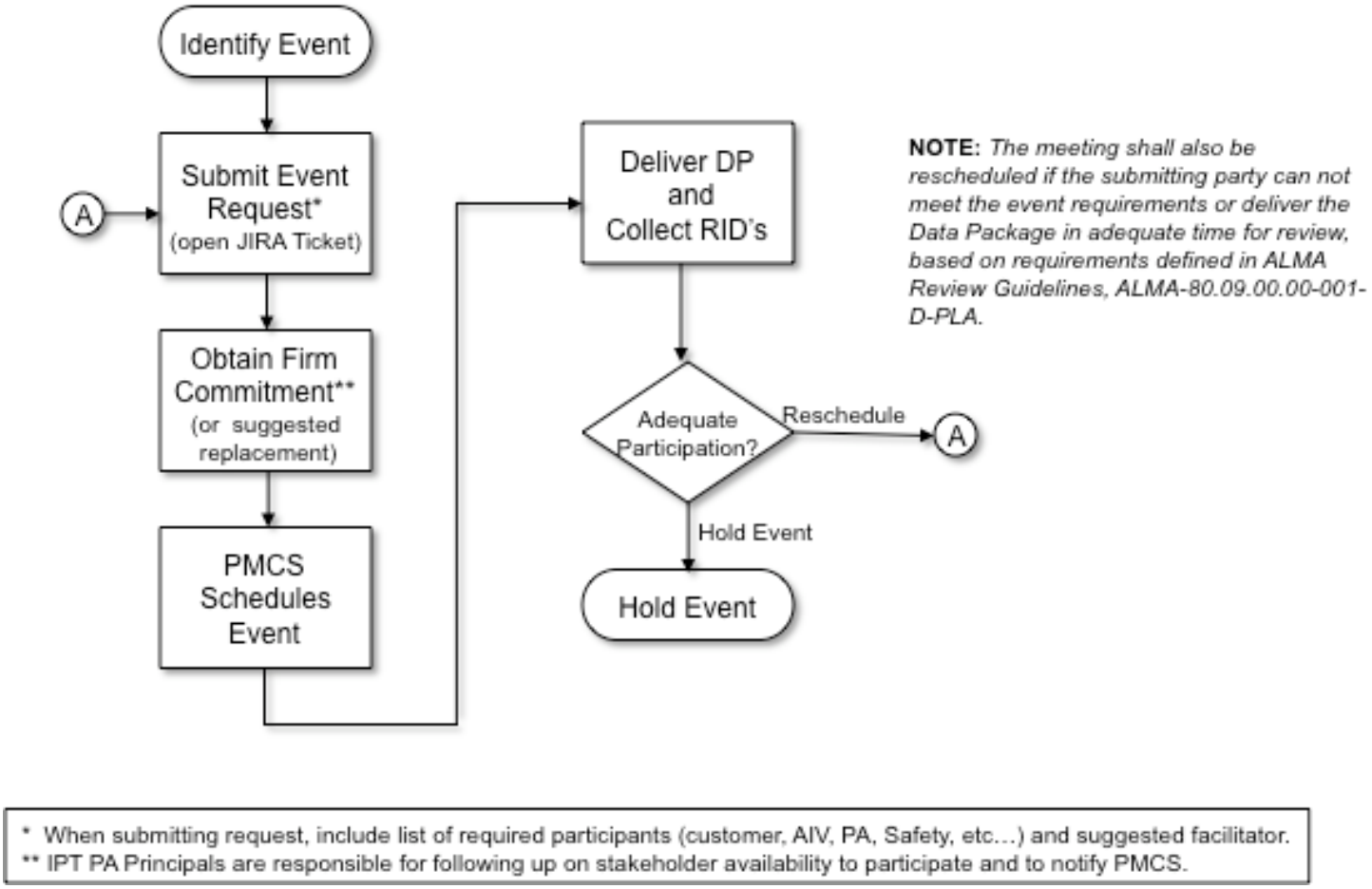

Figure 15: ALMA Event Scheduling Process