ALMA Product Assurance Requirements

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TABLE OF CONTENTS

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.
E.1	2018-11-08	All		First draft of rev. E, major update of these requirements for the ALMA Operations context

E.2	2019-06-03	All		Collaborative edition with corresponding Executive representatives
E.3	2019-07-03	All		Feedback received from IxT Managers incorporated
E.4	2019-08-07	All		Comments from Executive representatives incorporated
E.5	2019-09-27	All		Second round of feedback from IxT Managers incorporated
E.6	2019-10-14	Section 4.2.2		Requirement PA-00130 removed; editorial corrections for release
E.7	2020-01-15	All		Comments from K. Saini in response to ALMA-80.11.00.00-0111-A-CRE incorporated
E	2020-03-26	All	ALMA-80.11.00.00-0111-A-CRE	Editorial corrections from S. Rossi included, PAI acceptance team composition clarified; further alignment with the ALMA Development Projects Implementation Plan

1 PURPOSE

This document describes the Product Assurance (PA) management requirements applicable to the Atacama Large Millimeter/submillimeter Array (ALMA) Observatory, to satisfy all the reliability, maintainability, and quality requirements, and to ensure the success of mission throughout the phases in design, fabrication, test, and operation of the ALMA system.

2 SCOPE

These PA requirements shall be applied to equipment for all major upgrades (see definition in section 3.4) and new developments, including software, supplied to the ALMA observatory. For the ALMA Development Project Implementation Plan please refer to [AD10]. This document describes PA activities related to the specification, design, procurement, manufacture, delivery and acceptance of every hardware and software item under configuration control.

In case of conflict between the requirements of this document and Executive PA rules, the existing Executive rules shall have precedence.

It is noted that quality assurance/control activities related to on- and off-site maintenance of hard- and software are not within the scope of this document.

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, and the latest version shall apply unless otherwise specified.

Applicable Document List		
Reference	**Document Title**	**ALMA Doc. Number**
AD1	(DELETED in rev. E)	
AD2	(DELETED in rev. E)	
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	(DELETED in rev. E)	
AD6	(DELETED in rev. E)	
AD7	ICT Guidelines for ALMA Development Studies and Projects	COMP-70.05.00.00-0078-A-PRO
AD8	ALMA Safety Manual	ALMA-10.08.00.00-0011-D-MAN
AD9	ALMA Warranty Policy	ALMA-10.00.00.00-0016-A-PLA
AD10	ALMA Development Projects Implementation Plan	ALMA-10.04.00.00-0025-A-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	(DELETED in rev. E)	
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-C-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	MOU	Memorandum of Understanding
ADP	Acceptance Data Package	MRB	Material Review Board
AI	Action Item	MRR	Manufacturing Readiness Review
ALMA	Atacama Large Millimeter/Sub-millimeter Array	NA	North America
AMT	ALMA Management Team	NCR	Non-Conformance Report
CCB	Configuration Control Board	ORR	Operational Readiness Review
CDMR	Critical Design and Manufacturing Readiness	PA	Product Assurance
CDR	Critical Design Review	PAI	Preliminary Acceptance In-house
CI	Configuration Item	PAS	Provisional Acceptance on-Site
CIDL	Configuration Item Data List	PCB	Printed Circuit Board
CMMS	Computerized Maintenance Management System	PDR	Preliminary Design Review
COTS	Commercial Off The Shelf	P&QM	Performance & Quality Manager
CRE	Change Request	QA	Quality Assurance
DAR	Document Approval Request	RFW	Request for Waiver
EA	East Asia	SA	South America
EMC	Electromagnetic Compatibility	SE	System Engineering
EU	European Union	TBD	To Be Determined
IxT	Integrated Team (The x stands for E=Engineering, C=Computing, S=Science or Sop=Science Operations)	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 IxT 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 or product.

Conditional Acceptance: The status granted by the receiving party or customer, usually the JAO, allowing delivery and/or hand-over of (partially) unverified or non-compliant work products in an effort to facilitate further testing, design verification/adjustment, or putting a subsystem in production in a more suitable environment. All action items that were agreed related to the conditional acceptance must be addressed before full acceptance can be recommended.

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 with the goal of more thoroughly verifying requirements. Engineering Models must complete the ALMA acceptance process with focus on safety and interfaces prior to ultimate handover to the observatory, or be replaced with a fully (performance) 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.

Handover Process: Corresponds to the formal process where the responsibility for operation and maintenance of deliverables is transferred to the JAO. It is strongly linked to the incremental Acceptance Process, and it culminates when the ALMA Director, based on the recommendation issued by the Observatory System Engineer during the Acceptance Process, confirms the handover to the JAO of the deliverable for future operation and maintenance. In this context also a related Handover Certificate can be issued.

Major Upgrade: Improvement, upgrade and/or enhancement of the design of a subsystem that is deemed necessary to be managed as a separate project.

Owner: The organization (company, institute, etc.) who is legally owning 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 IET 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.

Validation Test: Tests performed are used to confirm that the (sub-)system is able to accomplish its intended use.

4 PRODUCT ASSURANCE MANAGEMENT

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

Considering that in the ALMA Operations phase PA aspects mostly relate to major upgrades and to new developments (HW and SW), the focus of PA management shall lie on an effective establishment and oversight of these PA requirements at the corresponding, specific development or major upgrade projects. In terms of resources, this implies that an ALMA PA Manager role (or its equivalent) shall be maintained at the JAO, while individual development projects shall appoint an according PA responsible. As there is no dedicated ALMA PA team in Operations, the development/upgrade project shall be responsible to provide and manage PA aspects.

4.1 JAO Performance & Quality Manager

{PA-0001.0-01/I} The JAO Performance & Quality (P&Q) manager (or his/her equivalent) shall be responsible for the implementation of the PA requirements presented in this document.

{PA-0002.0-01/I} The JAO P&Q Manager 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-0003.0-01/I} The JAO P&Q Manager shall be responsible for:

1. Oversight and management of PA principles at the ALMA Observatory site and related facilities.
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 and ACRV events performed at the OSF/AOS.
4. Management and tracking of Action Items from process audits at the OSF/AOS.
5. Guidance and coordination of PA aspects with the corresponding development/upgrade project teams.

4.2 Projects that Involve Hardware Modifications/Deliverables

{PA-0004.0-01/I} ALMA Executives or related partner institutes that perform major upgrades[1] and/or new developments that involve hardware modifications/deliverables shall identify responsible persons for PA concerns specific to a development project, hereafter referred to as, "PA Principal."

{PA-0005.0-01/I} Each major upgrade and/or new development project shall adhere to the PA requirements defined in this document.

{PA-0006.0-01/I} If a project 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 JAO P&Q Manager and the approval must be referenced in the tailored IxT PA Plan.

Request for Waivers (RFWs) related to Product Assurance requirements require approval from the ALMA Configuration Control Board (CCB) and the ALMA Director.

4.2.1 Planning and Reporting

{PA-0090-01/I} For each development project, the scope and frequency of PA updates shall be defined by IxTs and subcontractors, in order to ensure PA requirements remain in consideration throughout the project.

4.2.2 Procurement Controls

The requirements in this section apply to the purchase orders and contracts prepared for an ALMA IxT 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 Manufacturing Readiness Review (Section 7.1.5). In cases of conflict between this document and Executive procurement rules, the existing Executive rules will have precedence.

{PA-00100-01/I} The PA Principal shall participate in the preparation of material, component, process or manufacturing specifications in close cooperation with design and test engineers.

{PA-00110-01/I} The PA Principal shall review the sections related to quality assurance of 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.

[1] For the definition of "major upgrade" please refer to section 3.4.

{PA-00120-01/I} The Project Manager 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-00140-01/I} The Project Manager 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 or with 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 or with the ALMA system at its final location in Chile.

{PA-00150-00/I} When commercial-off-the-shelf (COTS) equipment or components are purchased for the first time, 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 PA Principal prior to the purchase of any equipment.

4.3 Projects that Involve Software Modifications/Deliverables

{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 and validation 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.
- Adequate documentation will be provided with deliverable software to allow the ALMA project to accept, use and maintain the software.

{PA-00965-00/I} All new software products, major software updates or software components part of a new subsystem development or upgrade shall follow the ICT Guidelines for ALMA Development Studies and Projects [AD7]. Specifically, software must be designed and organized to facilitate straightforward integration into the ALMA software repository and final handover to ICT. All technology choices must be coordinated with and approved by ICT.

5 PROJECT DOCUMENTATION

{PA-00175-00/I} The project's PA Principal shall identify the project-specific ALMA Deliverable documentation and seek approval from the JAO P&Q Manager. The following items shall be covered, though the JAO P&Q Manager can recommend the reduction of scope, or recommend the addition of documents, in order to tailor the documentation package to the specific needs of each project:

- Applicable specifications and requirements;
- External and internal Interface Control Documents (ICDs);
- Design reports;
- Design analysis reports, incl. reliability and maintainability analysis;
- Product Assurance and Safety Plans;
- Safety compliance report and hazard analysis;
- Electrical design, environmental and EMC compliance assessments;
- Product Assurance records/summaries, RfWs, CREs and non-conformance reports;
- Verification test reports;
- Acceptance test reports;
- Compliance matrix;
- Subsystem integration and -test plans;
- Subsystem commissioning plan;
- Validation test reports;
- As-built drawings;
- Bills of material;
- Operations and maintenance manuals;
- Configuration Item Data List (CIDL);
- Any other document that contains information necessary for the due verification, validation, acceptance, operation, maintenance and disposal of the development project's deliverable.

{PA-00176-00/I} The JAO P&Q Manager shall maintain an ALMA Document Approval Matrix that identifies the categories of the ALMA Deliverable Documentation, including the definition of who (in terms of roles) shall review, approve and release these documents.

{PA-00177-00/I} The approval of the ALMA Document Approval Matrix, or of any changes to it, shall follow the ALMA Change Control Process (CCB process).

{PA-00180-01/I} Approval, release and revision of ALMA Deliverable Documentation shall be performed following the procedures defined in Documentation Control Plan [AD4]. At a minimum, Version Control and Configuration Management processes shall be applied to all project documentation.

{PA-00182-00/I} Specifically, each ALMA Development Project shall issue a Product Assurance Plan that is tailored to the specific circumstances of each project, which is to be reviewed by the JAO P&Q Manager no later than the preliminary design review (PDR). This document is intended to provide sufficient and executable PA guidance to the project team and be in full compliance with the requirements contained herein. At a minimum, the Product Assurance Plan shall contain the following elements:

- Designation of PA Principal;
- Specific guidance on conformance to ALMA PA requirements, for example (note: contents may vary depending on the scale and nature of the project):
    - Documentation and Configuration Control;
    - Quality and Reliability of Parts and Materials;
    - Performance and Requirements Verification;
    - EMC Compliance;
    - Procurement Control;
    - Non-conformance and Issue Tracking;
    - Risk Management;
    - Shipping and Storage;
    - Inspections;
    - Test Reviews;
    - Acceptance Process;
    - …
- Planned project reviews and associated PA deliverables;
- Audit plan that details the scope of both internal (project team) and external (vendor) audits (if/as applicable);
- Approved waivers from ALMA PA requirements (if applicable).

6 CONFIGURATION ITEM MANAGEMENT

The following subsections outline requirements associated with the management of configuration items (CIs).

6.1 Configuration Item Identification

{PA-00190-01/I} Each ALMA Development Project 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-00200-01/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.

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 [RD11].

{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. When a CI is modified by the JAO, it shall work closely with the corresponding design authority in order to fulfill this requirement.

{PA-00270-01/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 IET, the responsible IET 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 PRODUCT 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.

7.1.1 Conceptual Design Review

The purpose of the Conceptual Design Review (CoDR) is to inform the JAO and other ALMA partners about details of a proposed Development Project.

{PA-00291-00/I} The decision-making authority related to the Development Project proposal shall decide whether a Conceptual Design Review shall be carried out, or not.

{PA-00292-00/I} At a minimum, the following points shall be evaluated during a Conceptual Design Review:

- Performance of new capabilities and/or improvements for the alternative design choices considering the science objectives and the organization’s long-term development strategy;
- Performance of improvements to that of the existing design;
- Likely changes of the science- and system level requirements as a result of the new development;
- Proposed methodology for evaluating the design alternatives;
- Planning of early design activities for the project, resulting in the selection of the baseline design.

7.1.2 (Sub-)System Requirements Review

Any ALMA Development Project or upgrade must be consistent with the latest applicable ALMA system- and sub-system level requirements. If additional specifications are necessary, or existing requirements need to be changed, this shall be subject to a (Sub-)System Requirements Review (SRR).

{PA-00295-00-I} The Observatory System Engineer shall decide whether a (Sub-)System Requirements Review must be performed for a specific Development Project proposal, or not.

{PA-00296-00-I} At a minimum, the following points shall be evaluated during a (Sub-)System Requirements Review:

- Changes of the science- and system level requirements as a result of the new development are consistent with the ALMA development roadmap and/or other, applicable strategic goals;
- Applicable requirements have been duly identified, are correct and complete.

7.1.3 Preliminary Design Review

{PA-00300-01/I} Product assurance shall be addressed as a review item at each 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-00330-01/I} The additional requirements and deliverables for the PDR are defined in ALMA Design Reviews Definitions, Guidelines and Procedure [AD3]. At a minimum, the following points shall be addressed:

- It shall be confirmed that requirements and external interfaces are complete and validated;
- It shall be demonstrated that the proposed design can meet the requirements;
- All major risks have been identified and mitigated;
- It shall be assessed if the project is ready to proceed to detailed (critical) design.

7.1.4 Critical Design Review

{PA-00340-01/I} Product assurance shall be addressed as a review item at each 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-00370-01/I} Failure modes and their effects shall be assessed during the design and development process and presented as part of each project's Critical Design Review.

{PA-00380-01/I} The additional requirements and deliverables for the CDR are defined in ALMA Design Reviews Definitions, Guidelines and Procedure [AD3]. At a minimum, the following points shall be addressed:

- It shall be verified that the detailed design of the configuration items satisfies specified requirements;
- The compatibility among the configuration items and other items of equipment, facilities, software, and personnel shall be established;
- Risk areas for each configuration item shall be assessed;
- As applicable, the results of producibility analyses shall be assessed, preliminary hardware product specifications shall be reviewed, preliminary test planning and the adequacy of preliminary operation and support documents be evaluated;
- Single point failure modes shall be identified;
- Likely failure modes and the resulting impact on the specific subsystem shall be identified;
- Critical items shall be identified and listed for review, and
- The failure rates of critical items shall 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 [AD3].

7.1.5 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 [AD3].

7.1.6 Critical Design/Manufacturing Readiness

{PA-00450-01/I} In certain cases, and with the approval of the Observatory System Engineer and corresponding Development Project's decision-making authority, 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 [AD3], under the CDR and MRR sections of that document.

7.2 Design References

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.

Document number	Document title
ALMA-80.05.02.00-001-B-SPE	ALMA Environmental Specification
ALMA-10.08.00.00-003-B-SPE	ALMA System General Safety Design Specification
ALMA-80.11.00.00-001-D-GEN	ALMA Product Assurance Requirements
ALMA-80.00.00.00-004-A-SPE	ALMA Policy document on the use of metric and SI units
ALMA-80.02.00.00-016-A-SPE	Requirements and guidelines for identification and labeling of ALMA equipment
ALMA-80.05.00.00-001-C-SPE	ALMA Power Quality (Compatibility Levels) Specification
ALMA-80.05.01.00-001-B-SPE	ALMA System Electromagnetic Compatibility (EMC) Requirements
ALMA-80.05.00.00-004-B-STD	Standard for AC Plugs, Socket-Outlets, and Couplers
ALMA-80.05.00.00-005-C-SPE	ALMA System Electrical Design Requirements
ALMA-80.02.00.00-003-G-STD	ALMA Documentation Standards
ALMA-80.02.00.00-011-F-PLA	ALMA Documentation Control Plan
ALMA-80.05.00.00-009-B-SPE	ALMA Coordinate Systems Specification
ALMA-80.07.00.00-001-D-PLA	Interface Control Document Management Plan
ALMA-80.09.00.00-001-D-PLA	ALMA Reviews Definitions, Guidelines and Procedure
ALMA-00.00.00.00-002-A-PLA	ALMA Operations Plan
ALMA-80.04.00.00-005-C-SPE	ALMA System Technical Requirements
SYSE-80.10.00.00-002-B-REP	Seismic Design Specifications for ALMA-AOS and ALMA-OSF Project
ALMA-90.00.00.00-001-A-SPE	ALMA Scientific Specifications and Requirements

8 RELIABILITY, MAINTAINABILITY, AVAILABILITY

{PA-00490-02/I} All ALMA components and subsystems shall be shown, by demonstration, analysis or test, to meet the applicable reliability, maintainability and availability requirements.

{PA-00500-01/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 Critical Design Review 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-00510-01/I} The manufacturer shall prepare and deliver to the IET or project a 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-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.

10 TEST

10.1 Verification Testing

One methodology of verifying requirements is through "test". Verification testing corresponds therefore to the execution of these tests as defined in the Verification Matrix, in order to check if applicable requirements have been fulfilled.

{PA-00625-01/I} There shall be a Verification Matrix that tabulates how and at what stage each and every requirement is to be verified. Typical verification methods include: Test, Analysis, Inspection and Simulation.

{PA-00630-01/I} Verification testing shall verify all requirements identified in the Verification Matrix as requiring a "test" as the method for verification.

{PA-00635-00/I} There should be a Verification Test Plan which identifies the specific conditions under which the requirements which need to be verified by test shall be tested.

{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.

{PA-00665-00/I} Each article shall come with a Compliance Matrix that will show the compliance status for each requirement.

10.2 Production Acceptance Testing

{PA-00670-01/I} Production acceptance testing shall be done on every piece, part, and component.

{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.

{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.

10.4 Test Witnessing

{PA-00730-01/I} The PA Principals, 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-00740-01/I} Before the start of verification/acceptance 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 of the Acceptance Test Plan.
2. Review 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-00750-01/I}The following personnel, at a minimum, shall be invited to participate in the review panel for a TRR: Sub-/system Systems Engineer, the PA Principal, Safety, and a representative from the receiving organization or customer (in most cases, this will be the Observatory System Engineer or the JAO P&Q Manager).

{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 clear 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-00775-00/I} Test data packages shall be stored in the ALMA Document Management System, in order to allow access to the data for future reference.

{PA-00780-00/I} If the electronic test data is provided via a network server, the corresponding file location, name and related access account information shall be provided.

{PA-00790-00/I} All test data submitted for verification or acceptance shall be duly packaged and released by the relevant organization.

{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 at a storage location that ensures long-term access as well as version control.

11 ACCEPTANCE CRITERIA

{PA-00805-00/I} Product acceptance shall follow an incremental approach:

1. Preliminary Acceptance In-House (PAI): shall focus on full acceptance verification in-house; if passed, the subsystem is authorized to be shipped to the site.
2. Provisional Acceptance on-Site (PAS): shall focus on a health check that the components have survived the shipping and transport process; if passed, the subsystem is authorized to be integrated at the site.
3. Acceptance Review (ACRV): shall focus on acceptance verification of the fully integrated subsystem; if passed, the subsystem is authorized to be commissioned. At this point all technical requirements shall have been duly verified.

{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 5;
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-00820-01/I} The following personnel, at a minimum, shall be invited to participate on the Acceptance Team for the PAI meeting: the JAO Observatory System Engineer (or his/her delegate), the Sub-/system Systems Engineer and/or Technical Lead, an Executive PA representative (as applicable) and the JAO P&Q Manager, IET-CL Lead (or delegate), and Safety. The Acceptance Team shall include corresponding representative(s) from the delivering ALMA Executive, and from the receiving organization or customer. The Observatory System Engineer, or his/her delegate, is the JAO representative formally authorizing shipment. If delegation is to occur, it will be defined in the event planning documentation.

{PA-00830-01/I} After successful completion of the PAI and approval of the customer, or in the case of work products delivered to the observatory, the Observatory Systems Engineer 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-00850-01/I} The following personnel, at a minimum, shall be invited to participate on the Acceptance Team for the PAS meeting: The Sub-/system Systems Engineer, the PA Principal, the JAO P&Q Manager, a JAO representative of the group that is going to operate and maintain the deliverable, Safety, representative from the receiving organization or customer (in most cases, this will be the Observatory System Engineer). The ALMA Director or his/her delegate, based on the recommendation made by the Acceptance Team, is the JAO representative formally authorizing acceptance. If delegation is to occur, it will be defined in the event planning documentation.

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/system/software and shall contain sufficient information for the installation, operation and maintenance of this equipment/system/software.

{PA-00870-01/I} The projects shall require delivery from subcontractors, if applicable, and deliver the documentation as applicable to the procured/built equipment/system/software. This deliverable documentation shall be referred to in its entirety as the 'Acceptance Data Package' (see Section 5 for details on Project Documentation).

{PA-00880-01/I} After review by the ACRV 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 (assuming that there are no blocking action items left), the product deliverable can be conditionally accepted by JAO for use in the observatory. Once all action items have been addressed and closure confirmed with the Acceptance Team, the deliverable can be recommended for full acceptance. Full acceptance shall be sought for all deliverables.

If the corresponding decision-making authority requests a formal Handover Certificate, and once full acceptance has been accomplished, an ALMA Acceptance Form [RD2] shall be created by or delivered to the Observatory System Engineer or delegate along with the acceptance report. The Observatory System Engineer or delegate, after review and approval, will deliver the report and form to the ALMA Director for review and signature.

{PA-00885-00/I} In terms of warranty, and as specified in the ALMA Warranty Policy [AD9], acceptance for warranty for deliverables from ALMA Development Projects is defined as occurring at the earliest of the following events:

a. Successfully passing PAS (provisional acceptance on site) or ACRV (acceptance review), whichever is applicable to the particular deliverable, or
b. The placement of the deliverable into routine use, or
c. Three months after delivery to the OSF.

13 ACTION ITEM TRACKING, REPORTING AND CLOSURE

{PA-00890-01/I} All issues identified during Development Project Level reviews (CoDR, SSR, PDR, CDR, MRR, CDMR) 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 IxT 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-00900-01/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 PA Principal is responsible for entering and maintaining the status of all action items.

14 RISK MANAGEMENT PROCESS

Within each development/upgrade project, the related technical, performance, quality, operational, schedule, organizational and cost risks, among others, need to be managed.

{PA-001380-01/I} The PA Principals and the JAO P&Q Manager shall notify management of all risks identified during reviews, acceptance events, process audits and product inspections.

{PA-001390-00/I} The PA Principals shall establish and maintain a risk management process that allows to duly identify, analyze and evaluate risks, to implement risk mitigation, and to monitor and communicate relevant project risks.

15 REQUIREMENTS FOR PROJECTS INVOLVING HARDWARE DELIVERABLES

The requirements contained in this section are only applicable to those projects that include final hardware deliverables that are not commercially available off-the-shelve (COTS).

15.1 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.

15.1.1 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

15.1.2 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-00940-01/I} The test procedures shall also include a description of the theory behind the measurement technique, and the exact test configuration.

15.2 SHIPPING, HANDLING AND STORAGE

Projects that involve hardware deliverables shall generate shipping guidelines 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-00970-01/I} Each project 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-00990-01/I} Handling, storage, packaging and transportation shall be performed such as to prevent damage or degradation of the 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-001015-00/I} If the shipping and delivery plan calls for it, the application of shock-loggers shall be included. In this case, incoming inspections shall be performed in order to check the shock-loggers and to report any detected anomalies.

{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.

15.3 INSPECTION

15.3.1 Shipping Inspection

Once a product has been accepted for shipment by the receiving 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.

15.3.2 Workmanship Inspection

A Workmanship Inspection at the location of the product/deliverable is implemented prior to receiving work products from a subcontractor, IET or from a JAO group. The inspection is implemented to verify that the components are in general good condition, free of defects and are completely assembled.

{PA-001050-01/I} The PA Principal or his/her delegate shall perform a Workmanship Inspection prior to the acceptance event authorizing shipment, most typically a PAI event.

{PA-001060-01/I} The PA Principal for the receiving organization, or his/her delegate 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 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.

15.3.3 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-001080-01/I} The 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

15.4 SAFETY ASPECTS

It is noted that aspects related safety for personnel and for equipment are noted here for completeness, but that these are not part of the scope of ALMA Product Assurance, and separate, additional requirements and processes apply and shall be coordinated with the corresponding Executive's safety liaison.

{PA-001100-01/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 Executive's safety liaison.

{PA-001110-01/I} Safety assurance matters shall conform to the requirements defined in the ALMA Safety Manual [AD8] and with site specific Safety directives.

{PA-001120-01/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 [RD4].

{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.

15.5 NON-CONFORMANCE REPORTING PROCESS

The Non-Conformance Reporting (NCR) process provides a procedure to identify and track IET and JAO 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 IET, and to follow up non-conformances detected during the operation of the deliverable by the JAO.

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

{PA-001240-01/I} Each IET or production group within the IET manufacturing work products to be delivered to the project shall implement a formal NCR process.

15.5.1 NCR Identification

{PA-001250-01/I} All product issues identified during the manufacturing and acceptance processes shall be recorded within a NCR tracking system (defined and set up by each IET or project team).

{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 a 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.

15.5.2 NCR Tracking and Closure

{PA-001280-00/I} All NCRs 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-001290-02/I} All open NCRs shall be reviewed by the IET or project team on a periodic basis to determine the status and required actions. During these reviews, the assignees and due dates will be adjusted as needed.

{PA-001300-01/I} The PA Principal shall review all open NCRs periodically to verify that none are excessively overdue and that actions are being implemented to address the issues.

{PA-001310-00/I} Once the IET 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.

15.5.3 NCR Reporting

{PA-001360-01/I} A comprehensive list of all NCRs shall be delivered in the documentation package, typically as an attachment or addendum to the CIDL during PAI, PAS and/or ACRV events.