

PAT-1 Subpart H Quality Assurance Program

10 CFR 71

February 23, 2011

Richard Yoshimura
Department 6234
Sandia National Laboratories
rhyoshi@sandia.gov



PAT-1 Program

Manager – David R. Miller

E-mail – drmille@sandia.gov

Phone (505) 284-2574

Project Manager – Richard H. Yoshimura

E-mail- rhyoshi@sandia.gov

Phone (505) 845-8181

Quality Assurance – Clinton C. L. Lum

Email – cclum@sandia.gov

Phone (505) 284-3602

Manufacturing Support – Lyman Wes Chilton

Email – lwchilt@sandia.gov

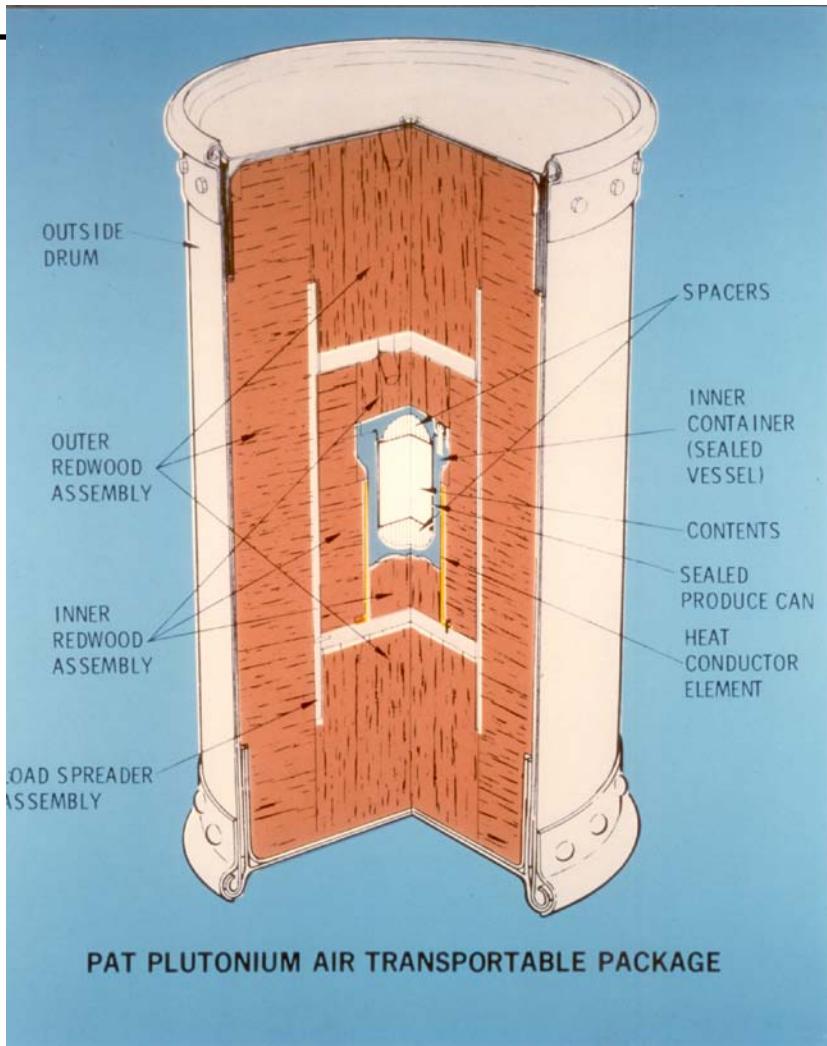
Phone (505) 844-0807



PAT-1 Air Transport Package (USA/0361/B(U)F-96)



- Major Components
 - AQ-1 Protective overpack
 - TB-1 SS Containment Vessel
 - PC-1 SS Product Can
- Gross Weight: 500 lb (227 kg)
- Dimensions: 24 1/2 in. (62.2 cm) dia. x 42 1/2 in. (108 cm) height





Section 9, PAT-1 Addendum

- Section 9 contains the quality program for PAT-1
- Supplements Section 9, *Specifications and Drawings, of the Safety Analysis Report for the Plutonium Air Transportable Package, Model PAT-1*
- Under umbrella of corporate SNL AS-PT-PD-04 *Title 10 Code of Federal Regulations Part 71 Packaging and Transportation of Radioactive Material – Quality Assurance Program Plan*
- Employs Quality Assurance Implementing Procedures (QAIPs) to supplement SNL corporate procedures to meet related elements of Subpart H



Section 9, PAT-1 Addendum - Continued

- Provides relationship of QA implementing documents and elements of 10 CFR 71 Subpart H
- Provides project tasks and quality categories
- Provides QA categories for design and procurement of new parts within the TB-1
- SNL Subpart H QAPP link, QAIPs, PAT-1 SAR Addendum available on internally on

\\snl\\NE_GS\\US\\PAT-1



Relationship of QAIPs to Subpart H

Table 9-1. Relationship between QA Implementing Documents and Elements of 10 CFR 71, Subpart H

Implementing Document ID	Title	Related Element of Subpart H	Description
AS-PT-PD-04 ⁶	<i>Sandia National Laboratories Title 10 CFR 71, Packaging and Transportation of Radioactive Material Quality Assurance Program Plan</i>	71.103 Organization	Describes the organizational roles, responsibilities, and relationships for activities and projects subject to 10 CFR 71, Subpart H, including packaging system recertification for the PAT-1 system.
AS-PT-PD-04 ⁶	<i>Sandia National Laboratories Title 10 CFR 71, Packaging and Transportation of Radioactive Material Quality Assurance Program Plan</i>	71.105 Quality Assurance Program	Describes the SNL QA program for activities and projects subject to 10 CFR 71, Subpart H, in general.
1071H-QAIP 2-2 ⁷	<i>Project Quality Plan Preparation</i>		Prescribes controls for preparing a Quality Plan specific to an individual project, e.g., PAT-1 Recertification.
1071H-QAIP 3-1 ⁸	<i>Design Control</i>	71.107 Package Design Control	Prescribes design control measures for packaging system items and components.
1071H-QAIP 9-2 ⁹	<i>Model Validation</i>		Prescribes control mechanisms applied



Relationship of QAIPs to Subpart H - Continued

1071H-QAIP 3-1 ⁸	<i>Design Control</i>	71.107 Package Design Control	Prescribes design control measures for packaging system items and components.
1071H-QAIP 9-2 ⁹	<i>Model Validation</i>		Prescribes control mechanisms applied to validating mathematical models used for analysis.
1071H-QAIP 9-3 ¹⁰	<i>Analyses and Calculations</i>		Prescribes controls applied to the conduct of analyses and calculations, including QA controls on software used for those analyses.
SNL Corporate Process Requirement 500.2.1	<i>Procurement Manual</i>	71.109 Procurement Document Control	Prescribes controls for preparation, content, and processing of procurement documents at SNL to ensure that applicable regulatory requirements, design bases, technical, and quality requirements are included or referenced in those documents.
1071H-QAIP 4-111	<i>Control of Procurement Documents and Purchased Material, Equipment, and Services</i>		Prescribes controls for preparation, content, and processing of procurement documents by procuring organizations other than SNL to ensure that applicable regulatory requirements, design bases, technical, and quality requirements are included or referenced in those documents.



Quality Assurance Implementing Procedures – Subpart H Elements

- 16 QAIPs were reviewed and approved by NNSA
 - 2-2 *Project Quality Plan Preparation* – 71.105 Quality Assurance Program
 - 3-1 *Design Control* – 71.107 Package Design Control
 - 4-1 *Control of Procurement Documents and Purchased Material, Equipment and Services* – 71.109 Procurement Document Control
 - 5-1 *Quality Assurance Implementing Procedure Preparation and Content* – 71.111 Instructions, Procedures, and Drawings
 - 6-1 *Document Review and Approval* – 71.113 Document Control
 - 6-2 *Document Control* – 71.113 Document Control
 - 8-1 *Identification and Control of Materials, Parts and Components* - 71.111 Instructions, Procedures, and Drawings
 - 9-1 *Control of Special Processes* – 71.119 Control of Special Processes
 - 9-2 *Model Validation Process* – 71.107 Package Design Control
 - 9-3 *Analyses and Calculations* - 71.107 Package Design Control
 - 9-5 *Technical Products and Deliverable Reports* – 71.121 Internal Inspection
 - 10-1 *Inspection and Identification of Item Status* – 71.121 Internal Inspection
 - 11-1 *Control of Data Collection and Testing Activities* – 71.123 Test Control
 - 12-1 *Control of Measuring and Test Equipment* – 71.125 Control of Measuring and Test Equipment
 - 13-1 *Control of Shipping, Handling, Storage, Preservation, and Cleaning* - 71.127 Handling, Storage, and Shipping Control
 - 15-1 *Control of Nonconformances and Corrective Action* – 71.33 Corrective Action



Graded Approach

Structures, systems, and components for which a failure or malfunction are designated

- **Category A** – could directly result in a condition that would adversely affect public health and safety
- **Category B** – could indirectly result in a condition that would adversely affect public health and safety only if the primary event occurs in conjunction with a secondary event or other failure or environmental occurrence
- **Category C** – would not significantly reduce packaging effectiveness and would be unlikely to create a condition that would adversely affect public health and safety



Quality Category C

- **Applicable quality requirements included in the purchase requisition, except when catalog or “off-the-shelf”**
- **Items and services received and used must be/are traceable to purchase documents and identified themselves/checked for damage prior to acceptance for use**
- **Traceability of modifications and/or changes to packaging components by updating documentation and distribution to appropriate individuals/organizations**



Quality Category B

- **Formal and documented quality program, shall exist, documenting compliance with applicable quality requirements**
- **Design shall be based on most stringent industrial codes and standards**
- **Required tests and inspections shall be performed using qualified individuals. Training/testing of personnel to applicable codes and standards shall be documented in department/corporate training records**
- **Non-Destructive Testing (NDT) examination personnel shall be qualified to ASNT-TC-1A**



Quality Category B - Continued

- **Design output documents shall be approved by appropriate engineering personnel**
- **Computer codes used in activities affecting quality, such as design analysis and verification, shall be validated for their application**
- **Documented test procedures shall be prepared for each testing activity; design verification could be done through alternate calculations/analysis only**
- **Measuring and test equipment shall be calibrated against standards traceable to NIST, where applicable**



Quality Category B - Continued

- **Procurement of items affecting safety shall be performed in accordance with SNL Procurement Manual and Quality-Significant Procurement process, as appropriate. Ensuring suppliers have quality program meeting the applicable requirements of 10 CFR 71 Subpart H**
- **Non Conformance Reports (NRCs) prepared and resolved for items determined to be outside of specifications**
- **Qualified personnel (auditors and lead auditors) shall perform quality audits**



Quality Category A

- **Category A item controls demands full implementation of all elements of QAPP, except where not applicable. Category A controls include**
 - **Design shall be based on most stringent industrial codes and standards**
 - **Appropriate engineering personnel shall review and approve design drawings**
 - **Design verification shall be performed by either formal design review or by physical testing, or both**
 - **Suppliers and sub-tier suppliers shall have quality program fully meeting applicable requirements of Subpart H**



Quality Category A - Continued

- **Required inspections/tests shall be performed by qualified personnel; training/testing to applicable codes and standards documented**
- **Welding of items affecting quality shall be performed by qualified personnel using certified equipment and processes**
- **NDT personnel shall be qualified to ASNT-SNT-TC-1A**
- **Computer codes used in activities affecting quality (design analysis and verification) shall be validated for their application**
- **Documented test procedures shall be prepared for design verification for item acceptance**



Quality Category A - Continued

- **Measuring and test equipment shall be calibrated against standards traceable to NIST, where applicable**
- **Designs specify traceability of raw materials used in package fabrication**
- **Certified Material Test Reports (CMTRs) or Certificates of Conformances (CoCs) shall be required, where specified in design documents, for raw materials used in package fabrication**
- **Procurement documentation for items/services affecting safety shall be prepared in accordance with Procurement Manual and Q-Sig Handbook**



Quality Category A - Continued

- If procured items affecting safety accepted at seller's facility, acceptance process delineated in contract with seller
- NCRs prepared and resolved for items determined to be outside of specifications
- Qualified personnel (auditors and lead auditors) shall perform quality audits
- Ensure that proposed changes to Category A components are controlled in same manner as original components



Procurement of New and Replacement Parts – Q-Sig Procurements

- **Determining method of quality control**
 - **Dedication (shall)**
 - Assure that requirements for an acceptable item/service are specified in the PR
 - Verify critical characteristics of goods/services via test, inspection, or quality verification documentation during manufacture and/or receipt to reasonably ensure specified requirements are met
 - Document inspection results



Procurement of New and Replacement Parts – Q-Sig Procurements - Continued

– Supplier Quality Evaluation (shall)

- Conducted and documented prior to contract award
- Specified requirements are controlled under the scope of the supplier's quality program activities
- Evaluation criteria and necessary supplier controls are determined using a graded approach
- Evaluation is specific to the scope of the specified goods or services



Quality Significant Inspection Plan

CREATE INSPECTION PLAN

*** (mandatory fields)**

*** Inspection Plan Reference #** (your own internal number or name)

*** Description of Product/Service Being Purchased:**

Drawing/Specification Number:

*** Estimated Date of Receipt:** (mm/dd/yyyy)

(Optional) Buyer:

(Optional) Request# (Optional) PO#

*** Inspection Categories:** (Select categories to be inspected below)

<input type="checkbox"/> Documentation	<input type="checkbox"/> Visual
<input type="checkbox"/> Mechanical Measurements	<input type="checkbox"/> Mechanical Performance
<input type="checkbox"/> Physical	<input type="checkbox"/> Chemical
<input type="checkbox"/> Electrical	<input type="checkbox"/> X-ray
<input type="checkbox"/> Surveillance	

Inspection Category Selections



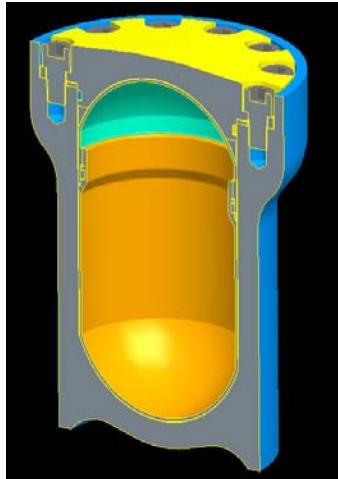
Example Inspection Category

Documentation

- Certificate of Conformance (COC)** (includes a statement of compliance to the drawings/specifications, quantity delivered, SNL contract reference, manufacturer lot, batch, run, etc., and actual manufacturer). Product labels of commercial items may provide a majority of COC requirements. If no additional specific product data is required, a COC is consequently unnecessary.
- Material Test Report**
- Material Certifications**
- Inspection Reports**
- Material Safety Data Sheet**
- Package Labeling**
- Part number**
- Certificate of Calibration**
- Diagram/Schematic**
- Software/Hardware/User Manuals**
- Other:**
- Other:**
- Other:**



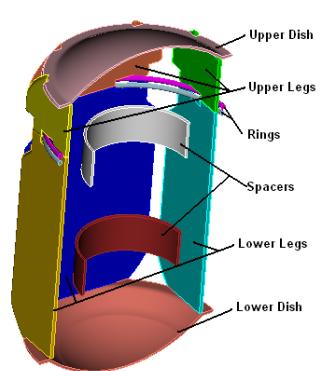
Titanium Packing Components in TB-1 Containment Vessel



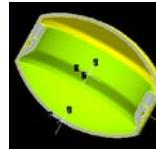
Ring Filler,
T-Ampoule
in TB-1



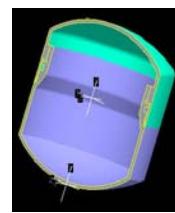
T-Ampoule



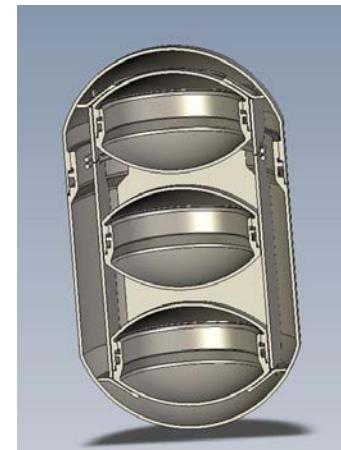
Inner
Cradle



SC-1



SC-2



Titanium
Components

- TB-1 Containment Vessel
- Titanium Components

PH13-8Mo
Ti-6Al-4V



Quality Categories for New Titanium and O-ring Components

Table 9-3. QA Categories for Design and Procurement of *T-Ampoule Assembly* and Inner Packing

Component Name	Drawing Number	Quality Category
<i>Ring, Filler</i>	2A0262	A
<i>T-Ampoule Assembly</i>	2A0261	A
<i>O-ring, Viton® for T-Ampoule</i>	2A0261, Item 3	C
<i>Inner Cradle</i>	2A0385	B
<i>Sample Container-1 (SC-1) Assembly</i>	2A0268	B
<i>Sample Container-2 (SC-2) Assembly</i>	2A0265	B
<i>O-ring, Viton for SC-1</i>	2A0268, Item 3	C
<i>O-ring, Viton for SC-2</i>	2A0265, Item 3	C



Titanium Components and Copper Seals

- Suppliers evaluated under PQR 1050 by Organization 423 Lead Auditor
- Crosswalk to 10 CFR 71 performed
- Jaguar Precision Machine Corporation was the successful bidder
- For titanium components, Section 1.3.3 in Addendum contains *PAT-1040 Titanium and O-ring Materials and Component Fabrication Specification*
- For copper seals, Section 9 of PAT-1 SAR provided specifications



PAT-1040 Titanium and O-ring Materials and Component Fabrication Specification

Topics Covered (in Addendum)

- **General** – provides summary of work to be performed, definitions, abbreviations/acronyms, requirements, references, technical submittals, QA requirements
- **QA requirements** – provides requirements for program, evaluation and approval, audits and assessments, qualification of vendor's inspectors, nonconformance reporting, receiving and inspection
- **Materials** – describes requirements for titanium and O-ring



PAT-1040 Titanium and O-ring Materials and Component Fabrication Specification - Continued

- **Fabrication** – describes equipment, product marking, surface finish
- **Packaging and Shipping** – describes requirements
- **Documentation** – provides requirements for documentation package
- **Other** – provides specific requirements for T-Ampoule titanium components fabrication and inspection.

O-ring Procurement for T-Ampoule

- Category C
- Invoice, Certificates of Conformance
- Viton Assurance
- Labeling



DATE: 12/09/10 01:32PM

PACKING LIST

Ship From
Southwest Seal & Supply
3825 Osuna Road NE Suite 6
Albuquerque NM 87109

Ship To
SANDIA NATIONAL LAB
ATTN: WES CHILTON
NM 87123

Bill To
Sandia National Lab
PO Box 5800
Accounts Payable MS1385
Albuquerque NM 87185-0978

Payment Terms	COD (3)
Ship Method	UPS Ground
Freight Terms	Prepaid
Customer Ship	SI150-01
Cartons	1
Weight	0.00
Tracking Nbrs	

Shipping Notes:

Customer PO: WES CHILTON 844-0807

Mark Number:

Packing List #:00032630

The following documents are required with each shipment:

Material Test Reports
Certificate of Conformance
Genuine Viton "A" Letter of Assurance

LINE	ITEM / DESCRIPTION	UOM	QUANTITY ORDERED	QUANTITY PRE SHIPPED	QUANTITY BACK ORDERED	QUANTITY THIS SHIPMENT
0020	2-241V75-AMS2817F O-RING VITON A, AMS-7276, Indv Pkg	EA	100.00	0.00	0.00	100.00

Certificate of Conformance

Company: Southwest Seal & Supply

P.O. # 00027340

This is to certify that the products supplied conform to the design and material Specifications and workmanship per the contract/purchase order requirements.

Quantity	Part Number	Batch Number	Cure Date	Material Type/Number	Shelf Life
100	2-241V75-AMS2817F	JJBV2	3Q10	VITON	Unlimited

PACKING; PREFORMED
QTY: 1 EACH
PKGD: 11/10 PER AMS 2817F
BATCH: JJBV2
CURED: 3Q10
PART ID#:AS568-241 V75
MFR P/N: 2-241V75-AMS2817F
MFR ID#: 1CN74
INT'L SEAL CO, SANTA ANA; CA.
MATL: CODE AMS7276G
MATL: CODE PER
ASTM D1418: FKM
AGE CONTROL NOT REQUIRED

Titanium Parts Procurement

- Category A, Print to Fab
- Quality Significant
- QA Program/PQR 1050
- Inspections
- Calibrated equipment
- CoCs, CMTRs
- Q-Sig Inspection Plan

INSPECTION PLAN

User ID: **lwchilt**

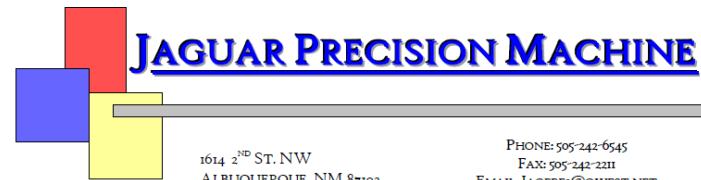
Unique Plan ID: **01-17-2011-11-20-28**

Inspection Plan Reference: **PAT-1 Titanium Components**

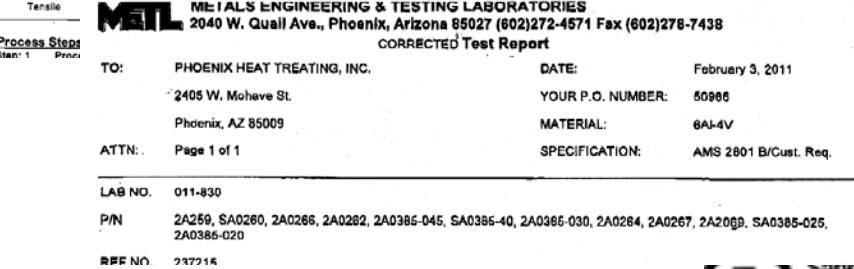
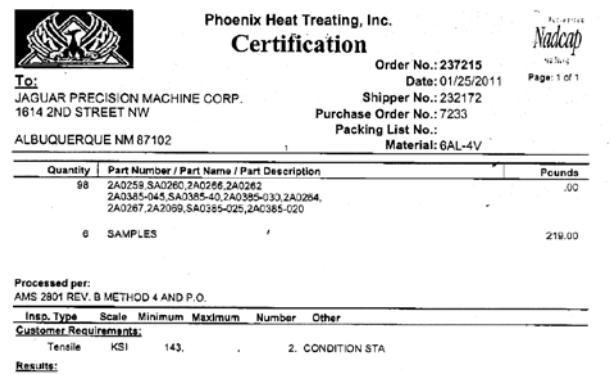
Description of Product/Service Being Purchased:

Plutonium Air Transportable Package Titanium Vessels; including sample containers 1 & 2, T-ampoule container, filler ring and inner cradle. Items to be fabricated to per Pat 1040 requirements and SAR drawings.

Drawing/Specification Number: 2A0261-2A0262-2A0265-2A0268-2A0285



Reviewed per PQR 1050



Copper Gasket Procurement

- Category A, Print to Fab
- Quality Significant
- QA Program/PQR-1050
- Inspections
- Calibrated Equipment
- CMTR, CoC
- Q-Sig Inspection Plan

INSPECTION PLAN

User ID: [lwhilt](#)
Unique Plan ID: [02-15-2011-9-27-25](#)
Inspection Plan Reference: [PAT-1 Gasket, Copper](#)

Description of Product/Service Being Purchased:
PAT-1 Gasket, Copper for TB-1 Vessel. Gasket to be made from "Copper Half Hard" 110 ETP or Up-dated mill description C11000. Vendor/contractor to be PQR 1050 certified by SNL.

Drawing/Specification Number: R00637, Rev. B

Receipt Date: 03/31/2011

Buyer: Eric Loehausen Request#: ML-12676 PO#: 1078628

Inspection Categories: (Categories previously selected to be inspected below)
Documentation(Part number), Documentation(Certificate of Calibration), Visual(Markings), Visual(Obvious Damage), Visual(Packaging), Mechanical Measurements(Width), Mechanical Measurements(Diameter), Mechanical Measurements(I.D.), Physical (Elongation), Physical(Hardness), Physical(Tensile Strength), Documentation(Certificate of Conformance (COC)), Documentation(Material Test Report), Documentation(Material Certifications), Documentation(Package Labeling)



Revere Copper Products, Inc.

PAGE: 1

CERTIFICATE OF TEST

CUSTOMER: TKMNA COPPER AND BRASS SALES
ATTN: ACCOUNTS PAYABLE
P O BOX 5116
SOUTHFIELD MI 48086-5116

MATERIAL: REVERE C11000 HALF HARD STRIP
ASTM B152

DATE: 01/10/2011
REVERE ORDER: 92183-C0463

CUSTOMER ORDER: 5400059217

JAGUAR PRECISION MACHINE CORP
1614 2ND St NW/Albuquerque, NM 87102

Invoice: 7435

CERTIFICATE OF CONFORMANCE

To: Sandia National Labs Date: 2/10/11
Purchase Order #: 1078628 Part No: R00637 Rev B

Description: Gasket, Copper

Qty 36 Serial: 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36,
37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48,
49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60

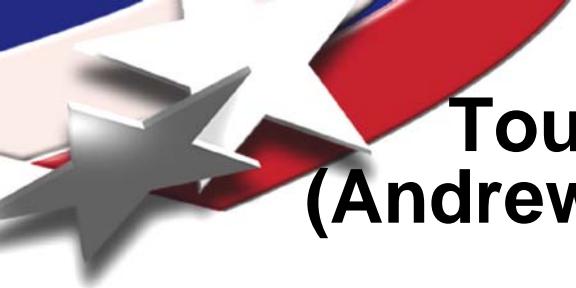
Seller certifies that:

1. These materials and/or parts were produced in compliance with all contractually applicable Government and/or Customer's specifications as referred in or furnished with the above P.O.
2. The materials and/or parts furnished under the above P.O. were produced:

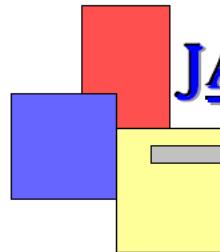


Other PAT-1 Replacement Parts

- **Quality Significant**
- **Dedication or Supplier Qualification depending on parts required.**
 - For commercial-off-the-shelf (COTS) components, use dedication process
 - For print-to-fab, use supplier qualification and/or dedication
- **Prepare Q-Sig inspection plan**



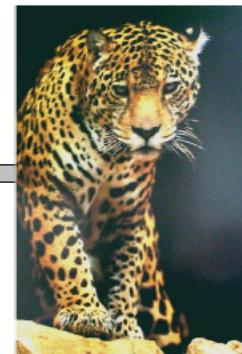
Tour of Jaguar Precision Machine (Andrew Sanchez, Manufacturing Liaison)



JAGUAR PRECISION MACHINE

1614 2ND ST. NW
ALBUQUERQUE, NM 87102

PHONE: 505-242-6545
FAX: 505-242-2211
EMAIL: JAGPRE3@QWEST.NET



- **Tour Facility**
- **Bonded Storage for Parts**
- **Quality Manual**
- **Calibration**
- **Procedures**
- **Certified Material Test Reports**
- **Certificates of Conformance**