

CORRECTIVE ACTION REQUEST

CAR No: 2005-2

Associated AR, SR, NCR No: AR 2005-1

PART A: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

Contrary to the requirements of TOP-012, Rev. 3, Chg. 0, a number of metal samples did not have the required identifications, the identifications were not properly maintained, or the sample control (sample location) log was not properly maintained:

1. One sample's identification was partially removed and not reestablished after machining. (Para. 4.1)
2. C22 plate in the machine shop missing required sample identification. (Para. 4.1)
3. Multiple bagged C22 test pieces, identification not carried over to bags. (Para. 4.2.2)
4. Sample custody log did not reflect correct location of C22 samples. One log entry missing and one entry showed the sample in two different locations. (Para. 4.3.2)
5. Sample control findings noted in the last two audits, ref. NCR 2004-13 and NCR 2003-10

Initiated by: R. Weber
Date: May 18, 2005

Responsible Individual: D. Dunn
Response Due: June 16, 2005

PART B: PROPOSED ACTION

1) Extent of Condition:

1. Several samples of cold rolled Alloy 825 were not individually identified and were not placed in the sample custody log. Markings on weld practice test plates were removed and/or faded.
2. The Alloy 22 plate in the machine shop was the only material in the shop. Specimens machined from the plate are often returned in unmarked containers.
3. All crevice corrosion test specimens identified in the audit have test identification, notebook number, and page number. The material heat number was added to all specimens as necessary. Several older specimens were stored in bags with faded markings. These bags were replaced.
4. Multiple entries into the sample custody log did not contain all mandatory information. Several materials do not have appropriate sample custody log entries. Multiple entries in the sample custody log used the TOP-004 form included with TOP-012 rev 3. This version of the form contains an error (Date of Initial Log Entry duplicated) and appear to have incomplete information.

2) Root Cause:

Staff are not sufficiently familiar with the detailed requirements of several procedures related to sample control. The requirements contained in these procedures for documentation associated with the purchasing, handling, storage, identification, and control of materials is not consistently practiced by staff performing these activities.

3) Remedial Action:

Proposed Completion Date: July 1, 2005

1. Heat numbers and appropriate identification information were added to the materials identified in Part B Section 1.
2. The Heat number was added to the Alloy 22 plate found in the machine shop in multiple locations.
3. Complete information including material heat numbers were added to bags containing test specimens. Bags with faded identification markings were replaced.
4. Incomplete entries in the sample custody log were corrected. The sample custody log was updated to include additional entries for cold rolled Alloy 825 material. Sample custody log entries using form TOP-004 included in TOP-012 Rev 3 were corrected.
5. Correct errors on form TOP-004 included in TOP-012 Rev 3.

4) Corrective Action to Preclude Recurrence:

Proposed Completion Date: July 30, 2005

1. Staff performing activities associated with the purchasing of material, confirmatory analyses, drawing control, and identification and control of material and test specimens will be retrained on procedures QAP-009, QAP-016, QAP-017, QAP-018, and TOP-012. The requirements of these procedures has been summarized in a training guide with specific examples on the purchasing requirements for materials, machining of test specimens, testing performed by vendors or other SwRI Divisions, and archiving of test specimens and material.
2. An additional form has been created to track the machining of test specimens. This form will be used for every machining operation using material identified in the sample custody log. The forms require entries to prior to delivery/shipment to the machine shop/vendor and after the receipt of the machined test specimens. Marked sample storage containers will be provided to the machine shops to contain completed test specimens. The sample storage containers will be marked with material identification, heat or lot number, test specimens identification (i.e. CNWRA Drawing number or ASTM or other test specimen identification).
3. Requirements of material identification for used test specimens have been reviewed. Specific instructions for the identification of test specimens will be posted on the sample containment cabinet. Used test specimens that do not need to be retained will be discarded.

Manager/Director: 

Date: 6/1/2005

PART C: APPROVAL
Comments/Instructions

Director of QA: 

Date: 6/1/2005

GEOSCIENCES AND ENGINEERING DIVISION

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<p>PART D: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION</p> <p><i>See below</i></p> <p>Verified by: <i>fr/beer</i> Date: <i>7/27/05</i></p>	<p>Distribution: Original-CNWRA/QA DIRECTOR QA Records ORIGINATOR PRINCIPAL INVESTIGATOR <i>D. DUNN</i> MANAGER <i>V. SAH</i> Asst. DIRECTOR <i>S. MATHIAS</i> CNWRA PRESIDENT GED VICE PRESIDENT</p>
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Remedial Action:

- ① Heat numbers and other information have been added to the sample bags. Verified by QA.
- ② Heat number is identified on the one remaining piece of C22 material in the machine shop.
- ③ Bags containing test specimens are clearly identified including heat numbers.
- ④ Sample custody log has updated and verified to include Alloy 825. Other corrections noted.
5. TOP4 form has been corrected.

Items 1-4 verified by MO SW CI QA, 7/25/05

Corrective Action to Prevent Recurrence:

1. Training on GEP-0015.019 was provided to affected staff on 6/14/2005. (attached)
2. A machining documentation form was prepared (attached)
3. Specific instructions for the identification of test specimens are now located inside the door of the sample containment cabinet. Verified by MO 7/25/05

Receipt, Handling, Storage, and Archive of Alloys, Materials, and Test Specimens

1. Relevant Procedures and Requirements:

TOP-012 Identification and Control of Samples and Chemical Reagents and Standards
QAP-009 Nonconformance Control
QAP-016 Procurement
QAP-017 Drawing Control
QAP-018 Procedure for Confirmatory Analyses

2. Purchasing Material Stock

2.1. When purchasing from a vendor not on the Approved Suppliers List, A purchasing plan is required (see QAP-016 section 3.1.2).

2.2. Q-codes should be included with purchasing documentation (QAP-016 Table 1)

Q3: Material certification
Q4: Mill test report
Q7: MSDS
Q11: Dimensional Inspection
Q12: Certified inspection/test data
Q20: CNWRA specific requirements
Q51: Certificate of analyses

2.3. Material to be purchased for testing should be properly described including Alloy Specifications and product form. This should include relevant ASME, ASTM, AMS, or AWS Standards. UNS numbers or other identification information

Example 1: Alloy 22 ASME SB575 UNS N06022
Example 2: ERNiCrMo-10 Filler AWS A5.14

2.4. A mill test report must accompany all commercial alloys (QAP-016; Q-code: Q4). The mill test report should identify the heat number, product form and product specifications (e.g. ASME SB-575 UNS N06022). A certificate of analyses must be included with specialty heats or materials.

2.5. Commercial alloys must undergo confirmatory analyses (QAP-018). The confirmatory analyses must be performed by a vendor on the Approved Suppliers List and should be the bases for acceptance of the material purchased. A copy of the confirmatory analyses must be placed in the scientific notebook along with the mill test report. Objective evidence should be included in the notebook to indicate the confirmatory analyses was reviewed and found acceptable.

2.6. An entry into the sample custody log must be completed after receipt of the material (TOP-012). The sample custody log should contain a cross reference to the scientific notebook entry documenting the purchasing and confirmatory analyses of the material.

3. Machining of Test Specimens

3.1. All materials, alloys and test samples must be identified at all times (TOP-012). For alloys, the complete heat number must be included on all material stock. All test

specimens must either be marked or placed in marked containers

3.2. Prior to shipping material to a vendor such as a machine shop, fabricator, or testing laboratory, the material must be appropriately marked (TOP-012). Alloys plates for machining of test specimens should include heat numbers, rolling direction and any other necessary information. Marked containers sufficient to accommodate the number and size of the specimens will be provided to suppliers performing services.

3.3. Materials to be machined into test specimens must be accompanied by a CNWRA approved drawing that includes dimensions and dimensional tolerances (QAP-017) or a drawing with dimensions from an appropriate standard (e.g. ASTM E399).

3.4. The sample custody log must be updated each time controlled material is provided to a machine shop for machining of test specimens (TOP-012).

3.5. Per QAP-016, test specimens must be accompanied with a dimensional inspection (Q-code: Q11). The dimensional inspection must be reviewed. If acceptable, a copy of the dimensional inspection must be placed in the appropriate scientific notebook. Objective evidence should be included in the notebook to indicate the dimensional inspection was reviewed and found acceptable (e.g. a statement that the dimensional inspection was reviewed and accepted).

3.6. Returned material stock should be inspected to verify the correct material was returned and all appropriate identifications are visible (TOP -012). Additional identification should be added as necessary.

3.7. A non conformance report is required for any of the following conditions (QAP-009)

3.7.1. Test specimens fail to meet the dimensional tolerances

3.7.2. Number of specimens was different than requested in purchasing documentation

3.7.3. Dimensional inspections were not supplied or are incomplete

3.7.4. Material stock was not returned

3.7.5. Material and or specimens were returned in an unmarked condition or unmarked containers

3.8. Receiving information will be placed in the sample custody log after material receipt (TOP-012). The receiving information will include notebook numbers and page numbers documenting purchasing requirements, dimensional inspections, and any non conformance reports

3.9. Receiving paperwork is forwarded to the Division 20 Financial Clerk. For accepted items "accepted" should be written on the receipt traveler (QAP-016). If the items are not acceptable, the non conformance report number should be included on the receipt traveler.

4. Testing performed by Vendors or Other SwRI Divisions

4.1. Vendors performing testing for Division 20 must either be an approved supplier or a purchasing plan must be written and approved prior to initiating the purchase requisition (QAP-016). Appropriate Q-codes must be specified. For testing or inspection the

appropriate Q-code is: Q12. The type of testing to be performed must be identified on the purchasing documentation along with any testing standard (e.g. ASTM E23).

4.2. Materials and or test specimens sent to vendors and or other SwRI divisions for testing must be appropriately marked (TOP-012). For alloys appropriate marking includes material identification and heat number. Test specimens must include alloy identification, heat number and the scientific notebook number and page number containing information on the test specimens (e.g. CNWRA drawing number, test specimen purchasing documentation and dimensional inspection. Appropriate pre-marked containers must be provided for the return on test specimens.

4.3. Purchasing documentation and the purchasing plan (QAP-016), if required, should be placed in the appropriate scientific notebook.

4.4. Upon receipt, the test specimens will be inspected and all test data will be reviewed (QAP-016). If required, the data will be included in the appropriate scientific notebook.

4.5. A non conformance report is required for any of the following conditions (QAP-009)

4.5.1. Test specimens failed to meet requirements or were inappropriate for the test

4.5.2. Number of specimens tested was different than requested in purchasing documentation

4.5.3. Test data were not supplied or are incomplete

4.5.4. Test specimens or materials were not returned

4.5.5. Test specimens or materials were returned in an unmarked condition or unmarked containers

5. Archive Samples

5.1. Archived raw materials should be marked with the material identification, and heat number (TOP-012). The purchase order number should also be included.

5.2. Archived test specimens should be marked or stored in containers with the following information

5.2.1. Test identification (e.g. C22R128)

5.2.2. Material identification (e.g. Alloy C22)

5.2.3. Material heat or lot number (e.g. 2277-8-3175).

5.2.4. Scientific notebook number for test information (e.g. Notebook 278)

5.2.5. Page number in scientific notebook. (e.g. Page 231)

CAR 2005-2

Corrective Action Item 2

Specimen Machining Documentation Form			
Purchase/Work Order Number			
Material Identification			
Material Heat Number			
CNWRA Requestor			
Vendor			
Specimen Description (CNWRA Drawing Number, ASTM Standard)			
To be Completed Prior to Order		To be Completed upon Receipt of Order	
Date		Date	
Material Supplied to Vendor (Y/N)		Remaining Stock Material Returned From Vendor (Y/N)	
Material Marked with Heat Number and Rolling Direction (Y/N)		Remaining Stock Material Marked with Heat Number and Rolling Direction (Y/N)	
Dimensions of Material stock provided (L x W x H)		Remaining Stock Material Dimensions (L x W x H)	
Specimen Quantity Ordered		Specimen Quantity Received	
Dimensional Inspection Required (Y/N)		Dimensional Inspection Provided (Y/N)	
Marked Containment Provided (Y/N)		Marked Containment Used (Y/N)	
Documented in Scientific Notebook Number/Page Number			
NCR Number (if applicable)			

Signature

Date