

1.0 POLICY/PURPOSE

SBAR, Inc. maintains documented procedures for the control of nonconforming products and services. SBAR is committed to locating nonconforming products and services as soon as possible in the system and ensuring that those products do not reach the customer. Further, SBAR is committed to identifying and documenting corrective and preventive actions necessary to eliminate the causes of actual or potential nonconformity. Additionally, when appropriate, SBAR procedures and work instructions are promptly revised as the result of corrective and preventive actions.

2.0 SCOPE

This operating procedure applies to all SBAR operating units within the Corporation.

3.0 REFERENCES AND DEFINITIONS

3.1 References

ISO 9001: Quality Management Systems-Requirements, Third Edition (2000-12-15)

• ISO 9001 Elements 8.3 (Control of Nonconforming Product), 8.5.2 (Corrective Action), 8.5.3 (Preventive Action)

SBAR Documentation

- SBAR Quality Manual(QAP 2000)
- SBAR Document and Data Control Procedure (CP-00-9005)

3.2 Definitions

<u>Concession:</u> Permission to use or release a product that does not conform to specified requirements. The Customer normally grants concessions.

Conformity: The fulfillment of a requirement.

<u>Corrective Action</u>: Steps taken to eliminate the cause of a detected nonconformity or other undesirable situation.

<u>Critical Nonconformance:</u> A serious nonconformity that requires immediate corrective and preventive actions. Critical Nonconformances are assessed when:

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- There has been or will be a failure to provide an important product or service as required by a specific contract or purchase order.
- There has been or will be a fine issued by a regulatory agency such as by OSHA, EPA, etc.
- A Customer has given SBAR formal notice that they are unsatisfied with SBAR's performance in a specific area. Examples include Corrective Action Reports (CARs), "cure" notices, etc.
- A serious nonconformity exists that may adversely affect ISO registration or continued registration.

Any SBAR executive or manager is authorized to issue a Critical Nonconformance, which is so identified in the PAR Database.

<u>Customer:</u> Recipient of a product provided by the supplier. A customer may be a commercial firm, an individual, or a government agency. SBAR is the supplier.

<u>Defect:</u> Non-fulfillment of a requirement related to an intended or specified use.

<u>Functional Area Manager (FAM):</u> A senior supervisory individual who is responsible for the leadership, direction, and overall success of an area such as procurement, operations and maintenance, specific contracts, logistics, quality, safety, engineering, financial, or other operating unit within the company. As it pertains to this procedure, FAMs are the individual/position responsible for correcting a specific nonconformance or potential nonconformance.

Nonconformity: Nonfulfillment of a specific requirement. A nonconformance can include, but is not limited to:

- Failure to meet a specific contractual requirement between SBAR and a customer.
- Subcontractor failure to meet a contractual requirement.
- Failure to comply with a generally accepted national, state, or local standard (e.g., American Society of Mechanical Engineers, Occupational Safety and Health Administration, American Bureau of Shipping, air pollution control district rules and regulations).
- Failure to comply with ISO 9001 or other relevant quality standard.
- Failure to meet a customer's expectations.

Operating Unit: An organization within the Corporation that is responsible for providing a product or service. An operating unit may be a department that is responsible for a complete

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product or service line, a group of dedicated personnel working on a specific contract, or an office, such as the Ventura office.

<u>Preventive Action</u>: Steps taken to eliminate the cause of a potential nonconformity or other undesirable potential situation.

<u>Process Action Report (PAR):</u> An electronic form used to report and document nonconformances, preventive actions, or process improvement actions. The PAR system is located in the PAR Database maintained at the web site. (**NOTE:** The PAR is the only form authorized for recording and documenting nonconformances, preventive actions, and process improvement actions unless otherwise authorized by the Quality Manager.)

PAR Database: The system for electronically recording and tracking all Process Action Reports (PARs) initiated by SBAR. Functional Area Managers, Quality Assurance Officers, Program/Contract Managers, and corporate officers have passwords for the site. Further, personnel are automatically advised of individual PAR status changes/updates via email.

Product: Result of activities or processes. A product may include service, hardware, processed materials, software, or a combination thereof. A product can be tangible (e.g., assemblies or processed materials), intangible (e.g., knowledge or concepts), or a combination thereof.

<u>Quality Assurance Office/Officer (QAO):</u> The SBAR agency responsible for managing the quality assurance program at the applicable level within the Company. QAOs are located at the corporate, division, and, when appropriate, the contract level.

<u>Service</u>: Service is the result of at least one activity performed at the interface between SBAR and a customer. Service includes actions taken by SBAR after delivery of the product, in accordance with the contract statement of work (SOW).

4.0 RESPONSIBILITIES

4.1 Corporate Quality Manager

The Corporate Quality Manager is responsible for developing and implementing this procedure.

4.2 Functional Area Manager (FAM)

The responsibilities of the FAM are as follows:

- Investigate the cause of each nonconformance documented on the *PAR*.
- Implement corrective and preventive actions and apply controls to ensure effectiveness.

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- Investigate potential problems and/or nonconformance documented on the *PAR*.
- Implement preventive actions and apply controls to ensure effectiveness.
- Ensure *PAR* forms are closed out as soon as possible.

4.3 Corporate/Operating Unit QAOs

The corporate/operating unit QAOs are responsible for the following activities:

- Manage their respective *PAR* programs.
- Assign the responsibility for each nonconformance and preventive action to the appropriate FAM.
- Verify corrective/preventive actions have been implemented prior to closing a *PAR*.
- Conduct follow-up on open *PARs*.

4.4 Operating Unit/Contract Program Managers

The senior manager for each operating unit or the contract program manager is the approving authority for closing actions on all *PARs*.. These individuals are ultimately responsible for the identification, prevention, and once discovered, the correction of nonconformances within their area of responsibility.

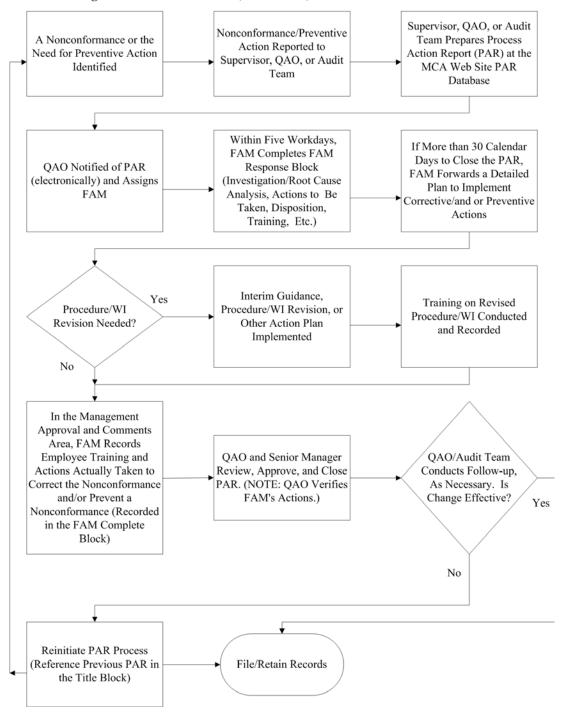
4.5 SBAR Webmaster

The Webmaster is responsible for the maintenance and improvement of the PAR Database.

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5.0 REQUIREMENTS/PROCEDURES

Figure 1 -- Nonconformance, Corrective, and Preventive Action Process



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5.1 Control of Nonconforming Products and Services

Figure 1 presents the process for nonconformance/corrective and preventive actions. Sources of nonconformance information include, but are not limited to:

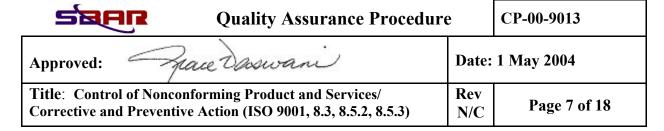
- Customer feedback received in any form (e.g., customer survey forms, email, telephone calls)
- Internal quality audits
- External quality audits
- Meetings
- Inspection activities on customer or subcontractor provided goods and services that do not meet requirements
- Employee feedback
- Any other sources where nonconformance is either alleged or implied

Upon discovering a nonconformance, the situation is immediately reported to the supervisor and/or the QAO. See *Attachment 1 – Instructions for Completing Nonconformance and Preventive Action Process Action Reports* for directions on how to initiate, process, complete, and record PARs via the PAR Database.

When appropriate, nonconforming products require segregation until they can be evaluated for disposition. Disposition could include:

- Rework of the product to meet specified requirements
- Acceptance of the nonconforming product by concession, with or without repair (**NOTE**: If a customer grants a concession, the concession is in writing/email from the customer and a record copy is maintained.)
- Rejection or scrapping of the product
- Alternative uses for the nonconforming product

When a nonconforming product is used or repaired, SBAR obtains written permission (e.g., email) from the customer (e.g., government contracting officer), when required by contract. The description of the accepted nonconforming product and any repairs is recorded. Records of detection and disposition of a nonconformance are maintained and a repaired and/or reworked product is re-inspected in accordance with the appropriate procedure or requirement. This information is recorded in the PAR per the Attachment 1 instructions.



5.2 Corrective Action

The responsible FAM determines what actions are needed to handle any problems requiring corrective action, initiates the preventive action, applies controls to ensure effectiveness, and when appropriate, implements customer directed disposition instructions. Therefore, within five working days of PAR receipt, the FAM completes the FAM Response block on the PAR per *Attachment 1 – Instructions for Completing Nonconformance and Preventive Action Process Action Report.* (**NOTE:** FAMs take immediate action on all Critical Nonconformances.)

The goal is to correct nonconformances as soon as possible, not later than 30 days; however, if a nonconformance cannot be corrected within 30 days, the applicable QAO continues to track the open nonconformance until corrective and preventive actions are complete. Further, in cases where the corrective and preventive actions are complicated or will take an extended period to implement, the FAM develops a detailed implementation plan (e.g., MS Project) to track and resolve the nonconformance. In any event, the FAM is still responsible for final corrective and preventive action and reports status to the QAO. Additionally, when appropriate, open PARs are discussed during management staff meetings.

Corrective and preventive actions are documented and implemented in a variety of methods, to include:

- Interim policy guidance (QA Guide) in accordance with SBAR *Document and Data Control Procedure (MCA-00-9005)*.
 - Procedure/work instruction revision.
 - Training/retraining.
 - Checklist revision, etc.

In any event, all personnel affected by the above are trained within five working days of release of the QA Guide, work instruction revision, checklist revision, etc. Further, this training is recorded in the PAR.

5.3 Preventive Action

Sources of information for potential problems or potential nonconformances include:

- Processes and work operations that affect product or service quality
- Concessions
- Internal and/or external audit reports

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- Quality records
- Service reports
- Customer complaints (e.g., meetings with customers, customer survey forms)
- Employee feedback (e.g., a technician reports that the preventive maintenance schedule for a specific piece of equipment needs to be changed in order to prevent equipment failure)

In these cases, see Attachment 1 – Instructions for Completing Nonconformance and Preventive Action Process Action Report for instructions for directions on how to initiate, process, complete, and record preventive action PARs.

5.4 Customer Feedback

When appropriate, the FAM or senior manager, informs the customer (e.g., customer Quality Assurance Officer, Contracting Officer or Program Manager) in writing/email of the nonconformance, the corrective action, and the preventive action. Again, per *Attachment 1 – Instructions for Completing Nonconformance and Preventive Action Process Action Report*, this action is recorded in the applicable PAR.

5.4 Nonconformance and Preventive Action Aging Reports

Graphs showing monthly trends on the average time (in days) for completion and closeout of nonconformance and preventive actions are depicted in the PAR Database, Management Reports section. These graphs are briefed at all Quality Steering Committee (QSC) Meetings and are a tool for senior management to gauge the effectiveness of the PAR system.

Attachment 1 – Instructions for Completing Nonconformance and Preventive Action Process Action Reports

Pathway/Instructions for PAR Database Entry

- 1. MCA web site
- 2. ISO 9001 Certified
- 3. PAR Database
- 4. *UserID* and *Password* (Contact QAO for assistance.)
- 5. Login
- 6. Once logged in, you can:
 - Initiate a nonconformance PAR, preventive action PAR, or a process improvement PAR, or
 - View/update specific PARs or select management reports (average days to close PARs and open PAR status)

NONCONFORMANCES

Initiating a Nonconformance PAR

- 1. In the *Location* block, if a pull-down menu is provided, select the appropriate SBAR location for the PAR. (**NOTE:** Pull-down menus are provided for personnel who have responsibility at more than one location.)
- 2. In the *Title* block, a brief description/name for the nonconformance is required, e.g., Uncalibrated Equipment in Use.
- 3. In the *Area* block, list the corresponding portion of the Quality Management System, e.g., Calibrated Equipment.
- 4. In the *Detailed Description of Problem* block, list specific details of the problem at hand, i.e., the "what, when, where, etc." Normally, do not list the name of the person who "caused" the nonconformance (it may not be their fault). For example, "At Bldg 7000, 2/1/03, a technician was using an uncalibrated fluke meter for a continuity check."

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- 5. In the *Critical?* Block, check Yes or No. For Critical Nonconformances (see paragraph 3.2, Definitions section of this procedure), immediate action is required by the FAM to correct the nonconformance.
- 6. In the *Supervisor / FAM Notified* (Date) block, enter the date that the pertinent supervisor / FAM was made aware of the nonconformance. This should always have happened by this point in the process.
- 7. In the *Requirement that was violated* block, list the specific reference, to include the applicable paragraph, for the nonconformance. Examples of acceptable references are:
 - ISO 9001, 7.6 (a).
 - LCC SOW paragraph 3.2.1.
 - 29 CFR 1910.24 (b).
 - EWR 127-1, paragraph 6.5.2.2.
 - SBAR Document and Data Control Procedure (CP-00-9005), paragraph 5.2.3.

(**NOTE:** If there is no specific reference, then most likely there is no nonconformance and a process improvement PAR should be written.)

- 8. If the product needs to be segregated from conforming product, check Yes in the *Immediate segregation required?* Block. Next, in the *To where?* block, list the location of the nonconforming product.
- 9. In the *Recommended Solution* block, make a recommendation as to how to correct the nonconformance and prevent future recurrence. Include any reasonable inputs from the personnel who are either responsible for the nonconformance and/or will be charged with correcting the nonconformance.
- 10. Activate the *Save* button. The QAO for the nonconformance will automatically receive an email notifying them of the PAR.

QAO Assigns Roles

1. After receiving electronic notification of a PAR, the QAO logs onto the PAR Database, activates the *Assign Roles* link, and in the *QAO – Roles Assignment* block, the QAO selects the FAM who is responsible for correcting the nonconformance, the QAO who will be responsible for reviewing the PAR (**NOTE:** To avoid conflicts of interest, QAOs assign another QAO if there is a conflict of interest.), and the Senior Manager (*Sr Mgr*) who has overall responsibility,

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normally a contract program manager or equivalent. For all PARs initiated by a corporate officer, that officer will be the Senior Manager for that PAR.

2. The QAO activates the *Save* button and all interested parties are automatically notified of the PAR and role assignments.

The FAM Response

- 1. After receiving electronic notification of the PAR, the FAM logs onto the PAR Database, activates the *Add Response* link, and in the *FAM Response* blocks, the FAM takes the following actions:
 - Marks Yes or No in the *Environmental/Safety Concerns?* block.
 - Completes the *Investigation-What was the root cause?* block. See Attachment 2, Guidelines for Root Cause Analysis (The "Five Whys"). (**NOTE:** The QAO reviews the root cause analysis and if the analysis isn't sufficient, tasks the FAM to reaccomplish the *Investigation-What was the root cause?* block.)
 - Give details of what will be done to correct the nonconformance in the *What action will be taken?* block. Also, include those actions that will be instituted to prevent recurrence. (**NOTE**: The FAM needs to keep the QAO informed of planned actions to facilitate closure of the PAR.)
 - In the *ECD* block, list the estimated completion date. If the ECD is more than 30 days from the initiate of the PAR, a plan is required as to "when, who, where, how, etc." the nonconformance is to be corrected. Forward this plan separately to the QAO. (**NOTE:** If it becomes clear that the 30 day completion requirement will not be achieved, the FAM prepares a plan for correcting the PAR and forwards it to the QAO.)
 - The Customer Rep Approving Disposition block is used when the customer is notified of a nonconformance and they give direction as to what is to be done with the nonconforming product or service. In this block, list the name of the customer representative. (**NOTE:** Ensure the customer representative has the authority to give such direction, e.g., a Government contracting officer.)
 - The Disposition Instructions (if applicable) block reports the customer's disposition instructions
 - For the vast majority of PARs, the *Employees Briefing Required?* block is checked Yes.

- The *Customer Notification Required?* is checked Yes in the cases were we need disposition instructions, the nonconformance is identified by a customer, or senior management believes the customer should be notified.
- 2. The FAM activates the *Save* button and all interested parties are automatically informed that there has been a change in status for the PAR. (**NOTE:** The FAM is authorized to revise the *FAM Response* blocks as necessary.)

Management Approval and Comments

- 1. After PAR Database log on, activate the *Add Approval or Comment* button. In the *Type of Memo* block there are pull-down menus for:
 - Employees Briefed
 - Customer Notified
 - FAM Complete
 - QAO Approval
 - Sr. Mgr. Approval
 - Comment
 - PAR Closed

Comments/actions are recorded in the appropriate *Memo Text* block. Again, activate the *Save* button and all interested parties are automatically notified.

- 2. The FAM is responsible for the *Employees Briefed* block. As a minimum, this section records the fact that affected employees were briefed on the nonconformance and the corrective and preventive actions that have been implemented to prevent recurrence. Additionally, if a new procedure/WI is written or an existing one revised, the FAM documents the procedure/WI training. Examples of acceptable training *Memo Text* entries are:
 - See 2/1/03 training attendance form.
 - Personnel trained on this nonconformance via 2/1/03, 9:38 am email.
 - Personnel trained on this nonconformance and LO&SC-0014-11001-002, Rev A revision. See 2/1/03 training attendance form.

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(**NOTE:** The FAM and/or QAO maintain a record (electronic/paper) of all training used to close PARs.)

- 3. The FAM completes the *FAM Complete* block that should closely mirror the FAM's comments in the *What action will be taken?* block. In the *FAM Complete* block, the FAM records the actual corrective and preventive actions. Give specific details such as dates, name of new procedure/WI written, revision to existing procedure/WI, customer notification, etc. Again, these actions need to be coordinated with the QAO.
- 4. The QAO completes the *QAO Approval* block. The primary purpose of this block is for the QAO to verify and validate the actions of the FAM. In other words, has the nonconformance been corrected and is there sufficient preventive actions in place to preclude a recurrence? Give specific details such as, "On 2/2/03, QAO verified that all fluke meters have been accounted for and have been calibrated; all are entered into the PMEL system; technicains retrained 2/1/03; and that all PMI WIs have been revised to check the calibration status of all calibrated equipment prior to use."

(**NOTE:** For audit and Critical PARs, QAO schedules a reinspection/reaudit at a later date.)

- 5. The senior manger (e.g., program manager, corporate officer) completes the *Sr. Mgr. Approval* block and ensures the actions of the staff are acceptable. The senior manger adds any necessary comments in the *Memo Text* block.
- 6. The QAO completes the *PAR Closed* block after all actions have been completed IAW ISO 9001 and this procedure.

PREVENTIVE ACTION

Initiating a Preventive Action PAR

- 1. In the *Location* block, activate the pull-down menu for the location of the PAR. (**NOTE:** Pull-down menus are provided for personnel who have responsibility at more than one location.)
- 2. In the *Title* block, a brief description/name is required, e.g., Records Control/Retrieval.
- 3. In the *Area* block, list the corresponding portion of the Quality Management System, e.g., Quality Records.
- 4. In the *Detailed Description of Problem* block, list specific details of the problem at hand, i.e., the "what, when, where, etc." Normally, do not list names of persons involved. For example, "At Bldg 851, 2/1/03, project records are not always returned to the proper file cabinet after use."

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- 5. In the *Recommended Solution* block, make a recommendation as to how to prevent a nonconformance from occurring. Include any reasonable inputs from the personnel who have the most knowledge of the area of concern.
- 6. Activate the *Save* button. The QAO for the preventive will automatically receive an email notifying them of the PAR.

QAO Assigns Roles

- 1. After receiving electronic notification of a PAR, the QAO logs onto the PAR Database, activates the *Edit Roles* button and in the *QAO Roles Assignment* block, the QAO selects the FAM who is responsible for reviewing the preventive action, the QAO who will be responsible for reviewing the PAR (**NOTE:** To avoid conflicts of interest, QAOs assign another QAO if there is a conflict of interest.), and the Senior Manager (*Sr Mgr*) who has overall responsibility, normally a contract program manager or equivalent. For all PARs initiated by a corporate officer, that officer will be the Senior Manager for that PAR.
- 2. The QAO activates the *Save* button and all interested parties are automatically notified of the PAR and role assignments.

The FAM Response

- 1. After receiving electronic notification of the PAR, the FAM logs onto the PAR Database, activates the *Edit Response* button and in the *FAM Response* blocks, the FAM takes the following actions:
 - Marks Yes or No in the *Is this request valid?* block.
 - Give details of what will be done to prevent a nonconformance in the *What action will be taken?* block. (**NOTE**: The FAM needs to keep the QAO informed of planned actions to facilitate closure of the PAR.)
 - In the *ECD* block, list the estimated completion date. If the ECD is more than 30 days from the initiate of the PAR, a plan is required as to "when, who, where, how, etc." the nonconformance is to be corrected. Forward this plan separately to the QAO. (**NOTE:** If it becomes clear that the 30 day completion requirement will not be achieved, the FAM prepares a plan for correcting the PAR and forwards it to the QAO.)
 - For award fee contracts and the preventive action can be claimed as an enhancement, check Yes in the *Is this an enhancement?* block. (**NOTE:** Potential enhancements are reported to the award fee board separately.)

- For the vast majority of PARs, the *Employees Briefing Required?* block is checked Yes.
- The *Customer Notification Required?* block is checked Yes in the cases were the potential nonconformance is identified by a customer or senior management believes the customer should be notified.
- 2. The FAM activates the *Save* button and all interested parties are automatically informed that there has been a change in status for the PAR. (**NOTE:** The FAM is authorized to revise the *FAM Response* blocks as necessary.)

Management Approval and Comments

- 1. After PAR Database log on, activate the *Add Approval or Comment* button. In the *Type of Memo* block there are pull-down menus for:
 - Employees Briefed
 - FAM Complete
 - QAO Approval
 - Sr. Mgr. Approval
 - PAR Closed

Comments/actions are recorded in the appropriate *Memo Text* block. Again, activate the *Save* button and all interested parties are automatically notified.

- 2. The FAM is responsible for the *Employees Briefed* block. As a minimum, this section records the fact that affected employees were briefed on the preventive action, i.e., the actions that have been taken to prevent a nonconformance. Additionally, if a new procedure/WI is written or an existing one revised, the FAM documents the procedure/WI training. Examples of acceptable training *Memo Text* entries are:
 - See 2/1/03 training attendance form.
 - Personnel trained on this preventive action via 2/1/03, 9:38 am email.
 - Personnel trained on this preventive action and LO&SC-0014-11001-002, Rev A revision. See 2/1/03 training attendance form.

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(**NOTE:** The FAM and/or QAO maintain a record (electronic/paper) of all training used to close PARs.)

- 3. The FAM completes the *FAM Complete* block that should closely mirror the FAM's comments in the *What action will be taken?* block. In the *FAM Complete* block, the FAM records the actual preventive actions. Give specific details such as dates, name of new procedure/WI written, revision to existing procedure/WI, customer notification, etc. Again, these actions need to be coordinated with the QAO.
- 4. The QAO completes the *QAO Approval* block. The primary purpose of this block is for the QAO to verify and validate the actions of the FAM. In other words, will the instituted preventive actions prevent a nonconformance? Give specific details such as, "On 2/2/03, QAO verified that all records are now returned to their file cabinets; a file sign-out/sign system has been instituted; and technicains trained 2/1/03 on the new procedures."

(**NOTE:** For potentially Critical Nonconformances, the QAO schedules an audit in the future to ensure compliance.)

- 5. The senior manger (e.g., program manager, corporate officer) completes the *Sr. Mgr. Approval* block and ensures the actions of the staff are acceptable. The senior manger adds any necessary comments in the *Memo Text* block.
- 6. The QAO completes the *PAR Closed* block after all actions have been completed IAW ISO 9001 and this procedure.

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Attachment 2-Guidelines for Root Cause Analysis (The "Five Whys")

A thorough root cause analysis for a reported nonconformance is essential for implementing the appropriate corrective action, and, more importantly, institutionalizing an effective preventive action to ensure there is no recurrence. Merely restating the nonconformance and accepting responsibility, though admirable, doesn't help ensure a lasting preventive action. Accordingly, the next few paragraphs explain the Five Whys.

Let's say, for example, "The sump pump failed, thereby causing the sump to overflow." is the nonconformance. Under the Five Whys methodology, keep asking "why" until you cannot break the problem down any further. Normally, going any lower than Five Whys is unproductive and, in many cases, you arrive at the root cause before the fifth Why.

Therefore, in the sump pump failure nonconformance, the root cause is:

- First Why?: The sump pump failed because there was no oil in the motor.
 - o Second Why?: There was no oil in the motor because the technician did not service the motor.
 - Third Why?: The technician did not service the motor with oil because the technician was not tasked to service the motor nor were they aware the motor needed servicing.
 - Fourth Why?: The technician was not tasked to service the motor with oil because there was no requirement established in the computerized maintenance management system, i.e., MP2.
 - o Finally, the Fifth Why?/Root Cause: The preventive maintenance instruction (PMI) for the sump pump does not require the oil in the sump pump motor to be serviced every six months as recommended by the manufacture.

As depicted by this example, it appears that there is a problem with the PMI program that requires attention. That's the area that requires management/supervisor attention to both correct the problem at hand and ensure there is no similar recurrence.

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PREPARATION, REVIEW, AND APPROVAL OFFICIALS

Prepared By:

I M Stone

R. W. Stone Lead Auditor

Reviewed By:

M. T. Schmoll

Director Corporate Programs

Reviewed By:

Ralph Chapman

Quality Assurance Officer, Ventura

Ralph Chapman

Approved By:

Grace Vaswani President/CEO

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