1.0 Purpose

The purpose of this document is to guide and direct the management of nonconforming process and product within the WES quality management system. This relates to the following clauses of the ISO 9001:2008 standard and the WES-WSC QMS.

8.2.3 – monitoring and measurement of process
8.2.4 – monitoring and measurement of product
8.3 – control of nonconforming product

This document also provides guidance on the relationship of these three requirements to clauses 8.5.2 and 8.5.3 regarding corrective and preventive actions.

Note that the term “product” also includes outputs that are generally referred as services in the day-to-day terminology of the WES-WSC community.

2.0 BACKGROUND

The ISO 9001 standard requires the monitoring and measurement of both process and product.

The standard requires that the organization:

a) Monitor and measure product characteristics at different stages of product realization to verify that requirements have been met.

b) Maintain evidence that acceptance criteria have been met.

c) Deliver the product only after planned arrangements have been completed.

d) Control product that does not meet requirements and keep records.

See Section 4 for the definition of non-conformance.
3.0 QMS REQUIREMENTS FOR NONCONFORMANCE TRACKING – Process Flowchart

3.1 Start: Non-conformance detected

3.2 Communicate the non-conformance to the manager/process owner

3.3 Determine impact

3.4 Determine course of actions

3.5 Action according to 3.4

3.6 CPAR required?

3.7 CPAR Q2-850-01

3.8 Communicate decisions results

3.9 Keep records

END
Procedure notes:

Each WES process must take the following steps to ensure that it meets the requirements of the WES-WSC quality management system and by extension, complies with the ISO 9001 standard:

3.1. Nonconformance (NC) detected and logged.
3.2. Communicate the non-conformance to the manager/process owner
3.3. The PO has to determine the impact of the nonconformance, and the importance of it.
3.4. The PO has to determine the course of actions between 7 choices and document justification:
   1-Do nothing
   2-Accept the non-conformance and release
   3-Correct the non-conformance
   4-Monitor the non-conformance
   5-Inform the appropriate process owner
   6-Escalate to CPAR
   7-Initiate an opportunity for improvement
3.5. Implement the decision taken in 3.4.
3.6. The PO has to determine if CPAR is required.
3.7. If yes, the PO has to follows the corrective and preventive actions request process. See Q2-850-01.
3.8. The PO communicates decisions results including to the NC originator.
3.9. The PO has to keep records of decisions.

4.0 SUPPLEMENTAL INFORMATION

Nonconformance definition:

A nonconformity occurs when we don’t fulfill a requirement. Product requirements are specified in many ways e.g. contracts, memoranda of agreement, service level agreements, government regulations, and internal service standards/charters. Nonconformities also occur when we have formally documented a process or procedure and then don’t follow it e.g. process descriptions documented for major WES activities and standard operating procedures established to control those activities.

Most statements of requirements don’t specify perfection - they allow tolerances that balance costs with needs. For example, automatic weather stations can’t operate without failure 100% of the time and it isn’t feasible to instantly bring them into service when they do fail. Performance agreements with customers set tolerances that recognize those realities. WES is in non-compliance when it exceeds those tolerances and this in turn constitutes a nonconforming product. This statement, however, does not preclude the need to identify and manage individual nonconformances.

Important points to consider when a non-conformance occurs:

   a) Identify the outputs that the process produces.
   b) Identify the activities that the process follows to produce those outputs.
   c) Determine what constitutes a nonconformity with respect to outputs and processes i.e. what criteria apply when deciding whether the output or process meets specified requirements?
d) Assess how information about nonconformities is currently managed; determine if the nonconformities are consistently identified and if so, whether there is related information concerning actions taken in response; determine whether the information is retrievable in a form that provides evidence of records of nonconformities and that enables further analysis.

e) Assess how nonconformities are prioritized for action. Determine if procedures are required to ensure that high-priority issues receive appropriate levels of staff and management attention.

f) Identify the gap between the information needed and the information currently available using existing practices.

g) Develop a solution to minimize the gap.

These steps represent an idealized solution and managers need to recognize pragmatic concerns when implementing them:

a) Solutions need to make business sense. It may not be reasonable or cost-effective to track all products and processes – the choice is a matter of managerial discretion. Managers should, however, be prepared to explain their decisions in the context of a business case and risk analysis.

b) Many WES activities use operational processes to monitor their products. These are typically software-based processes and include logs and problem tickets. The resulting databases often include entries that are true nonconformities but these entries are often mixed in with ones related to scheduling, task management, etc. It may be more feasible to retain legacy practices – perhaps with some enhancement – than to redesign the process to optimize nonconformity tracking. The Nonconformity Report Form (QF-830-02) or equivalent is often a useful tool for supplementing legacy practices to meet the full requirements of the WES QMS.

To meet the minimum expectations of the QMS, the tracking mechanism must:

a) Address the major product offerings and operating processes.

b) Facilitate prioritization of critical issues.

c) Facilitate data analysis to identify trends.

d) Provide evidence of compliance to the WES QMS requirements.

5.0 SECTION RELATIONSHIP BETWEEN CPARs AND NONCONFORMITIES

In most processes, individual nonconformities are a fact of life and the operational systems deal with them on a routine basis. Some nonconformities, however, have the potential to significantly impact on the production process and on users. In other cases, frequent and related nonconformities – while not individually serious – may indicate a more serious underlying problem.

It may be possible to deal with even serious nonconformities at the working and supervisory levels. In other cases, senior managers may need to become involved but the solution lies within the authority and resources available to those managers. In such cases, procedures established to manage nonconforming product and process are often sufficient to address problem resolution.

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The Corrective and Preventive Action Request (CPAR) process (QF-850-01) comes into effect when these procedures do not bring the required results. Examples include cases where:

- A manager may not have enough authority or resources to take action and therefore requires support from peers and/or superiors.
- A manager receives from an internal supplier services that do not comply with standards or requirements.
- A manager is responsible for monitoring process or product but does not have the necessary authority to take actions required to resolve the problems detected through that process.

The CPAR process functions at two levels. The first is through the Nonconformity Report (NCR) (QF-830-02) or equivalent whereby the existence and nature of a problem are communicated to an appropriate person in the organization. When the NCR does not adequately resolve the issue, the full CPAR process comes into effect. This two-level process helps to avoid unnecessary administrative overhead and provides a document trail that is useful in communicating and understanding the issues.

In summary, nonconformance management and the CPAR process are not separate or parallel. The former includes the processes of identifying nonconformities to requirements, applying remedial actions, and analyzing the data for trends and systematic problems. The CPAR process follows sequentially in those cases where more senior levels of management need to be brought into play.

6.0 DOCUMENT HISTORY

Detailed History of Changes

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<tr>
<th>Rev#</th>
<th>Date</th>
<th>State</th>
<th>Initials</th>
<th>Description of Changes</th>
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<td>2006-12-15</td>
<td>Approved</td>
<td>EM</td>
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<tr>
<td>2Dv01</td>
<td>2007-08-08</td>
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<td>EM</td>
<td>Amendment in response to registration audit and CPAR 98</td>
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<td>2007-09-04</td>
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<td>JSC</td>
<td>Amendment in response to registration audit and CPAR 98</td>
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<tr>
<td>3A</td>
<td>2008-06-25</td>
<td>Approved</td>
<td>JV</td>
<td>Process revised in response to CPAR 98. Process now allows for the use of equivalents to forms used to record and track nonconformances, including electronic forms.</td>
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<tr>
<td>4A</td>
<td>2009-08-30</td>
<td>Approved</td>
<td>DL</td>
<td>Revised to resolve CPAR 214</td>
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<tr>
<td>5A</td>
<td>2009-09-28</td>
<td>Approved</td>
<td>EM</td>
<td>Service added to title. NC report reference number corrected and tied to NC process. New reference number QF-830-02</td>
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<td>6A</td>
<td>2010-11-22</td>
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<td>PT</td>
<td>Change document owner to Alain Boisvert (no other change)</td>
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<tr>
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<td>Approved</td>
<td>PT</td>
<td>Minor corrections</td>
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<td>8Dv01</td>
<td>2013-04-19</td>
<td>Draft</td>
<td>LCD</td>
<td>Document revised to ensure that it reflects all WES/WSC documentation procedures; clarification of notes and other</td>
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### Rev# | Date       | State | Initials | Description of Changes
---|------------|-------|----------|-------------------------------------------------
8Dv02 | 2013-04-22 | Draft | LCD      | Clarification of notes and other matters concerning documents.; added the flowchart and the procedure notes.
8Dv03 | 2013-04-25 | Draft | LCD      | Clarification of notes and other matters concerning documents.; updated the flowchart and the procedure notes. Added Section 5.
8A    | 2013-04-25 | Approved | AB  | Approved.
9Dv01 | 2014-04-03 | Draft | EH       | Changed link to latest version
9A    | 2014-04-03 | Approved | AB  | Approved
10A   | 2015-04-20 | Approved | AB  | Reviewed and maintain status quo, process subject to change due to release of ISO 9001:2015 standard. Proposal to potentially merge with Q2-850-01 Corrective and Preventive Actions common process.