Quality Content Work Group Update

OAGi Annual Plenary Nov 17, 2016

Scott Nieman, Land O’Lakes
Evan Wallace, NIST
Frank Riddick, NIST
Agenda

• Participants
• Origin
• Work to date 10.2.1
• Plans for 10.3
• 10.4 and Beyond
Core Team – Participants

- Bob Phare, Command Alkon
- *Frank Heinrich, iBaseT
- Keith Unger, Independent Consultant/ISA-95 Chair
- *Scott Nieman, Land O’Lakes
- *Frank Riddick, NIST
- *Evan Wallace, NIST
- *David Connelly, OAGi Staff
- Mike Rowell, Oracle / OAGi Staff
- Jim Wilson, OAGi Staff / AgGateway
- GUEST: Lakshmi Alapakam, Infor
Impetus of Quality Content Work Group

- Infor Submission just over 2.5 years ago
  - InspectionOrder
  - QualitySpecification
  - QualityTestMaster
  - QualityTestResult
  - CorrectiveActionPlan
  - DefectiveMaterialNotice
What problems are we trying to solve?

- Address gaps in the OAGIS related to Quality information exchange
- Address increased cross-industry focus on quality and transparency
- Communication of Quality requirements, based on product characterization
  - Test Specifications and Test Methods
  - Sampling Plans (AQL-based)
- Operational Needs
  - Inspection requests for positive release
  - Addressing nonconforming Material
  - Requesting and receiving Corrective Action Plans
  - Equipment Calibration/ Maintenance Schedule/ History
Level 4

Business Planning & Logistics
Plant Production Scheduling, Operational Management, etc.

Level 3

Manufacturing
Operations & Control
Dispatching Production, Detailed Production Scheduling, Reliability Assurance, ...

QMS / LIMS

Levels 2, 1, 0

Batch Control
Continuous Control
Discrete Control

Test Equipment, PLC, Sensors

Scope

ERP / PLM, Supplier Management
Recap: 10.2 Release – Nouns and Scenarios

• TestMethod
• TestSpecification
• InspectionOrder
• TestResults
• Updates to Item/BatchCertificateOfAnalysis and ItemNonconformance
• Published Seven (7) Scenarios
10.2.1 Fix

• 10.2.1
  – Fixed ComplexContent vs SimpleContent
# Bug Fixes for 10.2.2

**InspectionOrder**

<table>
<thead>
<tr>
<th>Element</th>
<th>Extends</th>
<th>Key Fields</th>
<th>Use Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Party</td>
<td>PartyType</td>
<td>Generic</td>
<td>InspectionOrder/Party</td>
</tr>
<tr>
<td>TestPackage</td>
<td>OpenCodeType</td>
<td>NA</td>
<td>InspectionOrder/TestRequest/TestPackage</td>
</tr>
</tbody>
</table>
Work Stream for 10.3

• Additional InspectionOrder capabilities
• Complete CorrectiveAction nouns
  – CorrectiveActionRequest
  – CorrectiveActionPlan
  – CorrectiveAction
• Scenario
  – Escalation of repeated ItemNonconformance
  – Escalation of SPC deviations
Additional InspectionOrder elements for 10.3
Land O’Lakes Request - Agronomist Need

<table>
<thead>
<tr>
<th>Element</th>
<th>Extends</th>
<th>Key Fields</th>
<th>Use Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>WorkOrderReference</td>
<td>OrderReferenceType</td>
<td></td>
<td>Field Operations, Tech Sales in Purina</td>
</tr>
<tr>
<td>ShipmentTrackingReference</td>
<td>OnlineDocumentReferenceType</td>
<td>Extended with ShipmentUnit</td>
<td>Scan QR code to lookup Shipment tracking Id</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Need the URI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Need the Shipper</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Need Number of Containers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Need ContainerIDs</td>
</tr>
<tr>
<td>AgriculturalParty</td>
<td>PartyType</td>
<td></td>
<td>Grower, Livestock Owner, and more!</td>
</tr>
</tbody>
</table>
Ag Parties
But wait! There is More!
Land O’Lakes 10.3 InspectionOrder Request

<table>
<thead>
<tr>
<th>Element</th>
<th>Extends</th>
<th>Key Fields</th>
<th>Use Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farm</td>
<td>LocationBaseType</td>
<td>Extended with Field</td>
<td>Grower has many Farms, Farm has many Fields</td>
</tr>
<tr>
<td>Field</td>
<td>IdentificationType</td>
<td>Extended with CoordinateBaseType ContextItem CropZone CropSeason</td>
<td>What is the best crop in this specific field for the crop season</td>
</tr>
<tr>
<td>CropZone</td>
<td>GeoPolygon</td>
<td>CropSeason</td>
<td>A field may have many crops in a given crop season, fields may have multiple crops on a field</td>
</tr>
<tr>
<td>CropSeason</td>
<td>EffectiveTimePeriod</td>
<td>ContextItem</td>
<td>Each calendar year may have many crop seasons, and a field may have many crops</td>
</tr>
<tr>
<td>GeoPolygon</td>
<td>Add string Field to CoordinateBaseType</td>
<td>Only new Field</td>
<td>Array of lat/long values, sequenced in order to form a polygon</td>
</tr>
</tbody>
</table>
Grower-< Farm -< Field Hierarchy

Grower has
Many Farms with
Many Fields
Plants in
Many CropZones
In a CropSeason

AWT
https://docs.oracle.com/javase/7/docs/api/java/awt/Polygon.html
GeoJSON uses AWT
### Additional InspectionOrder elements for 10.3

**Land O’Lakes Request - Purina Nutritionist Need**

<table>
<thead>
<tr>
<th>Element</th>
<th>Extends</th>
<th>Key Fields/Data</th>
<th>Use Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Livestock</td>
<td>TBD</td>
<td>Herd information, Livestock type, Name, Feed lot (separated if sick)</td>
<td>Nutritionist is creating a ration balance supplement formula, and needs to test existing on-hand feed (hay, silage)</td>
</tr>
</tbody>
</table>

More work needed
Correction Action - Business Context

- B2B integration with Suppliers and Customer’s Quality Management System (QMS), related to escalation process
- Internal Quality deviation alerts based on SPC rules (out of control indicators) and +/- 3 standard deviations (sigma)
- FSMA and other regulations call for Correction Action capability
- ISO 9000 calls out Corrective Action (since 1987)
Quality Management Business Capabilities

Quality Management System

Master Data Management
- Test Methods
- Test Specifications
- Regulatory
- Labs
- Facilities
- Equipment

Vendor Quality
- Vendor Management
- Nonconformance
- Incoming Inspection

Manufacturing Quality
- Lot Track and Trace
- Nonconformance
- Deviation
- Equipment Maintenance

Finished Goods Quality
- Certificate of Analysis
- Inventory Management
- Scrap
- Segregation
- Rework
- Reclassification

CAPA
- Incident Management
- Corrective Action Request Plan
- Corrective Action Implementation
- Audit
- Failure Mode Effect Analysis

Statistical Analysis
- Sampling Plan
- Sample Population
- Inspection Order
- Test Results
- SPC
- Multivariate
# Definition of New Nouns

<table>
<thead>
<tr>
<th>Noun</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CorrectiveActionRequest</td>
<td>A request to initiate a process to eliminate a reoccurrence of a nonconformity or deviation. The process will analyze data associated with the identified problem, identify causes, plan corrective action(s), implement corrective action(s), and verify that the action(s) have addressed the problem.</td>
</tr>
<tr>
<td></td>
<td><strong>AcknowledgeCorrectiveActionRequest</strong> acknowledges that the problem exists or not.</td>
</tr>
<tr>
<td>CorrectiveActionPlan</td>
<td>A formal description of the problem and the plan (including schedule) for eliminating its recurrence. This is typically offered to the party(ies) affected by the problem for approval prior to the plan’s implementation.</td>
</tr>
<tr>
<td></td>
<td><strong>AcknowledgeCorrectiveActionPlan</strong> acknowledges an agreement of proposed plan or not.</td>
</tr>
<tr>
<td>CorrectiveAction</td>
<td>Action(s) taken to eliminate the cause of a detected non-conformity or other undesirable situation (see Note 2 below).</td>
</tr>
<tr>
<td></td>
<td><strong>AcknowledgeCorrectiveAction</strong> acknowledges that the actions were verified and effective, or not.</td>
</tr>
</tbody>
</table>

Note 2 – Corrective action is taken to prevent recurrence … (from ISO 9000:2005 as quoted by the FDA)
Development Approach for 10.3 Corrective Action Nouns
Review Infor CorrectionActionPlan

• Analyzed Infor Submission
  – Realized it was a multi-purpose noun
  – ComplexTypes were based on state in the business process
• Considered a VBO-like concept -- not ready to take that on given 10.3 timeline
• Infor had reference to unbounded DefectiveMaterialNotice (history); we used ItemNonconformance
• Most of the concepts covered, with the exception of:
  – VirtualLocationIndicator – need to follow up
  – FinancialCalendarPeriod – look at EBO information; fiscal, calendar year
High Level Value Chain of Business Processes

1. Repeated Non-conformance (History)
2. Escalate to Corrective Action Request
3. Receive / Agree upon Corrective Action Plan
4. Implement Corrective Action
5. Verification / Measure Effectiveness
UML Sequence Diagram

- Created UML Sequence Diagram for incoming inspection of supplier shipment scenario
  - Identified key activities including internal activities
  - Discussed what types of information would be exchanged
  - Request/delayed response design pattern used throughout process
- Determined multiple nouns would be a better option
Drill down into UML Sequence Diagram

Could be qualitative (packaging, etc) or quantitative measure

NotifyShipment
ConfirmBOD

Perform Incoming Inspection
ProcessItemNonconformance()

ConfirmBOD

AcknowledgeItemNonconformance()

ConfirmBOD

Accept on Waiver/Concession
ProcessItemNonconformance()

Supplier Quality
Drill down into UML Sequence Diagram

:CustomerParty

ProcessItemNonconformance()
ConfirmBOD

:SupplierParty

Provide Correction

Supplier Quality

Cite ItemNonconformance history
- Lot/Date codes
- Test Methods failed/parameter summary
- Quantity failed
- Failure rate
- Speculated root cause
Process driving this
Need to resolve
Impact to manufacturing process; how painful is this?
Priorities; sense of urgency
Due date

formulateThePlan()
Drill down into UML Sequence Diagram

Supplier Quality

- Vendor Quality Review Board
- Brainstorming session / meet with Customer to discuss
- Meeting Notes references
- Escalation to other parties

- Quality:
  - More detailed root cause information
  - Step to fix
  - Investments to be made
  - Iterations (n #) to deploy; multiple facilities affected
  - Timeline
  - Verification process
  - Are there finer grained items we need to document
  - References to incident/ test results, and your speculated root causes

- Iteration #
  - When implemented
  - Verification information
  - Request for acceptance
  - Variations from the plan, expected to do one thing, but had to perform other activities due to various reasons
  - Document references
  - Images/ multimedia to prove
  - Statistical data / test results to illustrate that change has occurred; SPC control chart

- ProcessCorrectiveActionPlan()
- ConfirmBOD
- reviewSupplierProposedCorrectiveActionPlan()
- AcknowledgeCorrectiveActionPlan()
- ConfirmBOD
- ProcessCorrectiveAction()
- Confirm
- performAudit()
- AcknowledgeCorrectiveAction()
Data Sources

Additional Scope: Add Product Recalls

Source: Global Harmonization Task Force
Dr. Larry Kelly, GHTF Chair, Medical Device Industry
Mapping to Industry Models

Ideally, aerospace is compared to this model

Source: Global Harmonization Task Force
Dr. Larry Kelly, GHTF Chair, Medical Device Industry
# Examples of Escalation

<table>
<thead>
<tr>
<th></th>
<th>Scope / Data Analysis</th>
<th>What triggers an Escalation leading to CAR/CAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier Performance / Controls</td>
<td>Comparison to TestSpecifications and TestMethod capabilities</td>
<td>Repeated Item Nonconformance</td>
</tr>
<tr>
<td>Customer Complaints</td>
<td>Social Media, Service Requests</td>
<td>Customer Service data, Marketing</td>
</tr>
<tr>
<td>Market Survey</td>
<td>Quantitative, Statistical</td>
<td>Marketing Data</td>
</tr>
<tr>
<td>Process Controls</td>
<td>Quantitative, Statistical</td>
<td>Out-of-control, out-of-bounds rules</td>
</tr>
<tr>
<td>Quality Audits</td>
<td>Face-to-Face, Facility tours, data requests</td>
<td>Supplier Quality Engineer/Auditor discovered discrepancy/ anomaly</td>
</tr>
<tr>
<td>Returned Products</td>
<td>Quantitative, Statistical</td>
<td>Customer Service data, Regulatory, Customer Request</td>
</tr>
<tr>
<td>Recalls</td>
<td>Quantitative, Statistical</td>
<td>Regulatory, Industry visibility</td>
</tr>
<tr>
<td>Spare Parts Usage</td>
<td>Quantitative, Statistical</td>
<td>Excessive ordering of same part for repairs</td>
</tr>
<tr>
<td>Service Reports</td>
<td>Quantitative, Statistical</td>
<td>Number of repair work orders</td>
</tr>
</tbody>
</table>
### Scenario List

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Scenario Name/ Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC8</td>
<td>Corrective Action based on History of Nonconforming Items</td>
</tr>
<tr>
<td></td>
<td>Repeated vendor quality problem, requires rework, screening, and ultimately manufacturing process improvement</td>
</tr>
<tr>
<td>QC9</td>
<td>Corrective Action based on out of control manufacturing process</td>
</tr>
<tr>
<td></td>
<td>Worn equipment deterioration is identified by a series of measurements showing drift, and/ or outliers beyond +/- 3 standard deviations</td>
</tr>
</tbody>
</table>
BPMN Model for Incoming Inspection
Process Control Scenario

• Assessment of history

• Two common rule-based scenarios
  – Out of control; i.e., 5 measurement points in a row
  – Out of bounds > +/- 3 sigma; outlier detection

• There should be an analysis task performed by a Quality Control participant that may lead to a correction action

• Could be a Test Request (in-scope for our work group)

• Could be an Observation / Measurement off a sensor on the production line that could initiate
BPMN for Multiple Data Sources

Could be more iterations (loops) e.g., was the corrective action effective?
UML Class Diagrams

- Created class diagrams for each noun
- Specified OAGIS types when possible to speed up delivery
Corrective Action Request

class Corrective Action Request

- DocumentID: DocumentIDType
- LastModificationDateTime: DateTime
- LastModificationPerson: Person
- DocumentReference: DocumentReferenceType
- Status: StatusType
- ResponsiblePersonReference: PersonReferenceType
- CorrectiveActionPlanDueDate: DateTime
- CorrectiveActionDueDate: DateTime
  + ImpactOfProblem: Text
  + PriorityCode: OpenCodeType
  - RequestedTimePeriod: Period
  + ProcessStep: Text
  - CustomerParty: PartyType
  + SupplierParty: PartyType
  - ContractReference: DocumentID [0..1]

+ RequestedAction

+ RequestedInterimAction

+ RequestedAction [0..*]

Incident

- IncidentType: IncidentTypeType
- IncidentRecordReference: DocumentReferenceType [0..1]
- Item: ItemType
  + MaterialInstanceAffected: IdentificationType
  + TotalQuantityAffected: QuantityType
  + KeyTestResults: TestResultDetailType [0..*]
  + FailureRate: RateQuantityType
  + SpeculatedRootCause: Text [0..1]
  + Disposition: StatusType [0..1]
  - OrderReference: OrderReferenceType [0..1]
  + OrderType: TypeCode [0..1]
  + ProductReference: int
  - ProblemsIdentified: Text [1..*]

+ instanceNonconforming [0..*]

InstanceNonconformanceHistory

- ItemInstanceID: ID
- KeyTestResults: TestResultDetail [1..*]
- Disposition: StatusType [0..1]
- SpeculatedRootCause: Text [0..1]
Corrective Action Plan

class Corrective Action Plan

CorrectiveActionPlan

+ DocumentID: DocumentIDType
- DocumentReference: DocumentReferenceType [0..*]
- Status: StatusType
- CorrectiveActionRequestReference: DocumentReferenceType [0..*]
- ResponsiblePersonReference: PersonReferenceType [0..1]
- CorrectiveActionApproval: CorrectiveActionApprovalType [0..1]
- Item: ItemType [0..*]
- PlannedTimePeriod: TimePeriodType [0..1]
- ScheduledTimePeriod: TimePeriodType [0..1]
- Classification: ClassificationType [0..*]

+preventativeActions 0..* +correctiveActions 1..*

CorrectiveAction

+relatedActions 0..*
Corrective Action

For a given action, there may be many subjects that needs attention:
- People training
- Location: line
- Equipment: identifying a specific unit

VBO – like
Scenario 41

Case Management

Process

Acknowledge

Open Standards that Open Markets™
©
Timeline for Publication in 10.3

- 10.3 for CorrectiveAction related nouns
- 1Q17; XSD ready by middle of January
- Scenarios by 15-30 days after the XSDs mid Feb
Next Steps after 10.3

- SamplingPlan – simple SamplingProfile today
- RelativeLocation
- Uncertainty
- Expertise needed from other organizations; e.g., statistics, geospatial groups