



The New Normal for Supply Chain Integration

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Agenda



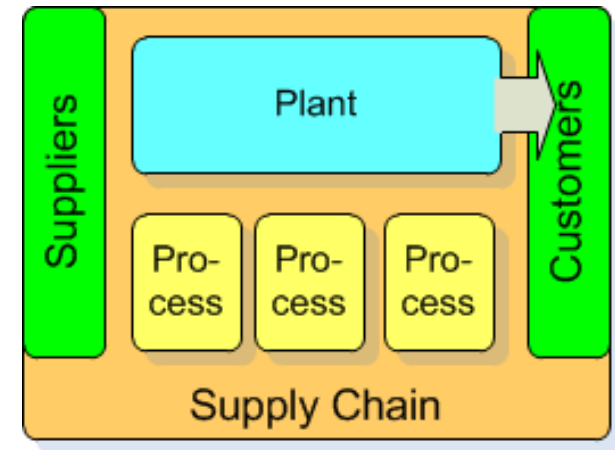
- The New Normal
- Market Trends / Drivers
- Functional Implications to MES and to the ERP Interface
- Enabling Technologies
- Summary



THE NEW NORMAL

The Old Normal

- Manufacturing Execution Systems (MES) are primarily focused on enforcement of work procedures and collection of batch record data for a process within a **PLANT** context.
- Material Management & Performance Management (i.e. asset performance) are typically supplied by other applications if they exist at all.

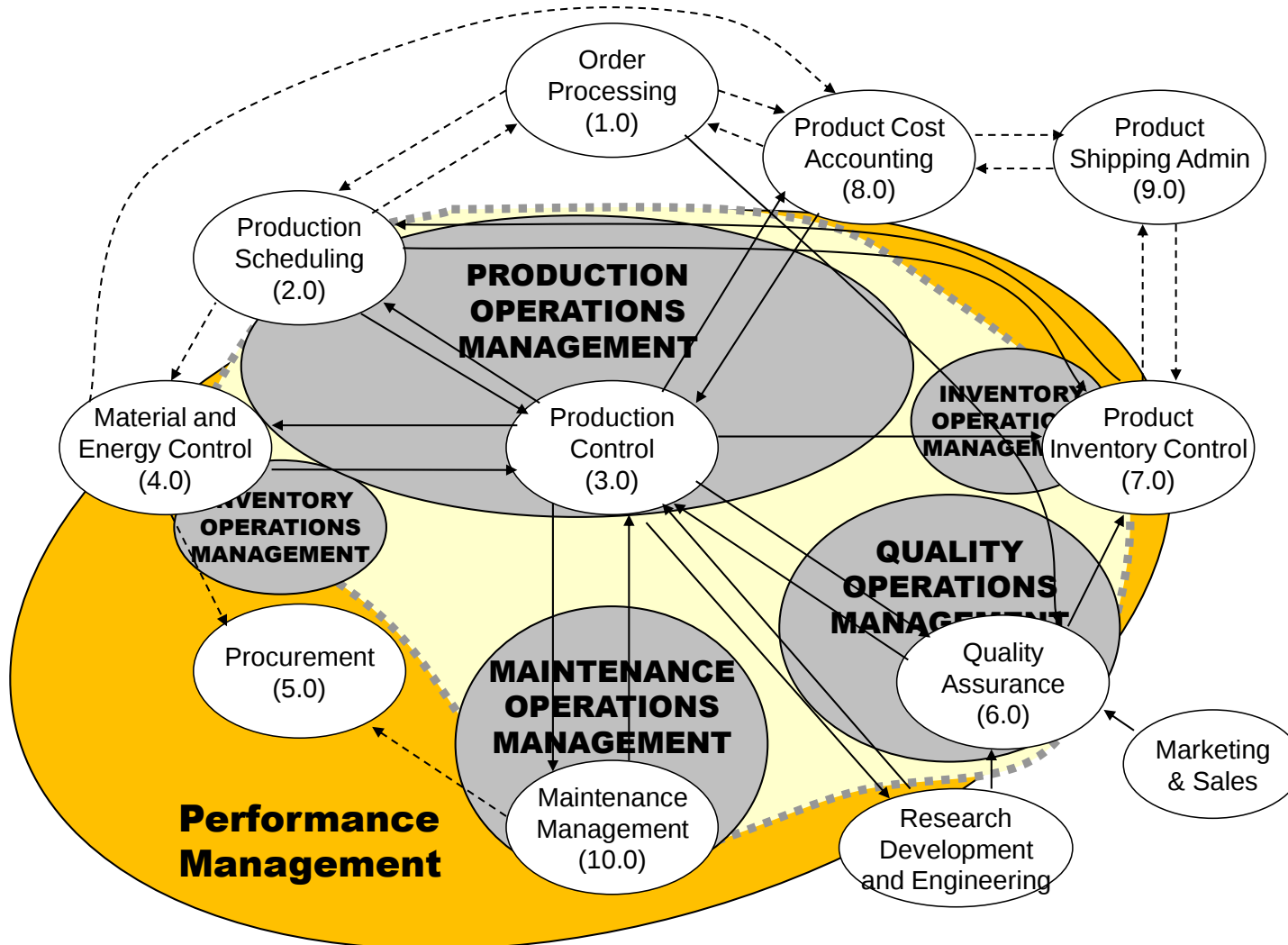


MES – “The Rodney Dangerfield” of Applications



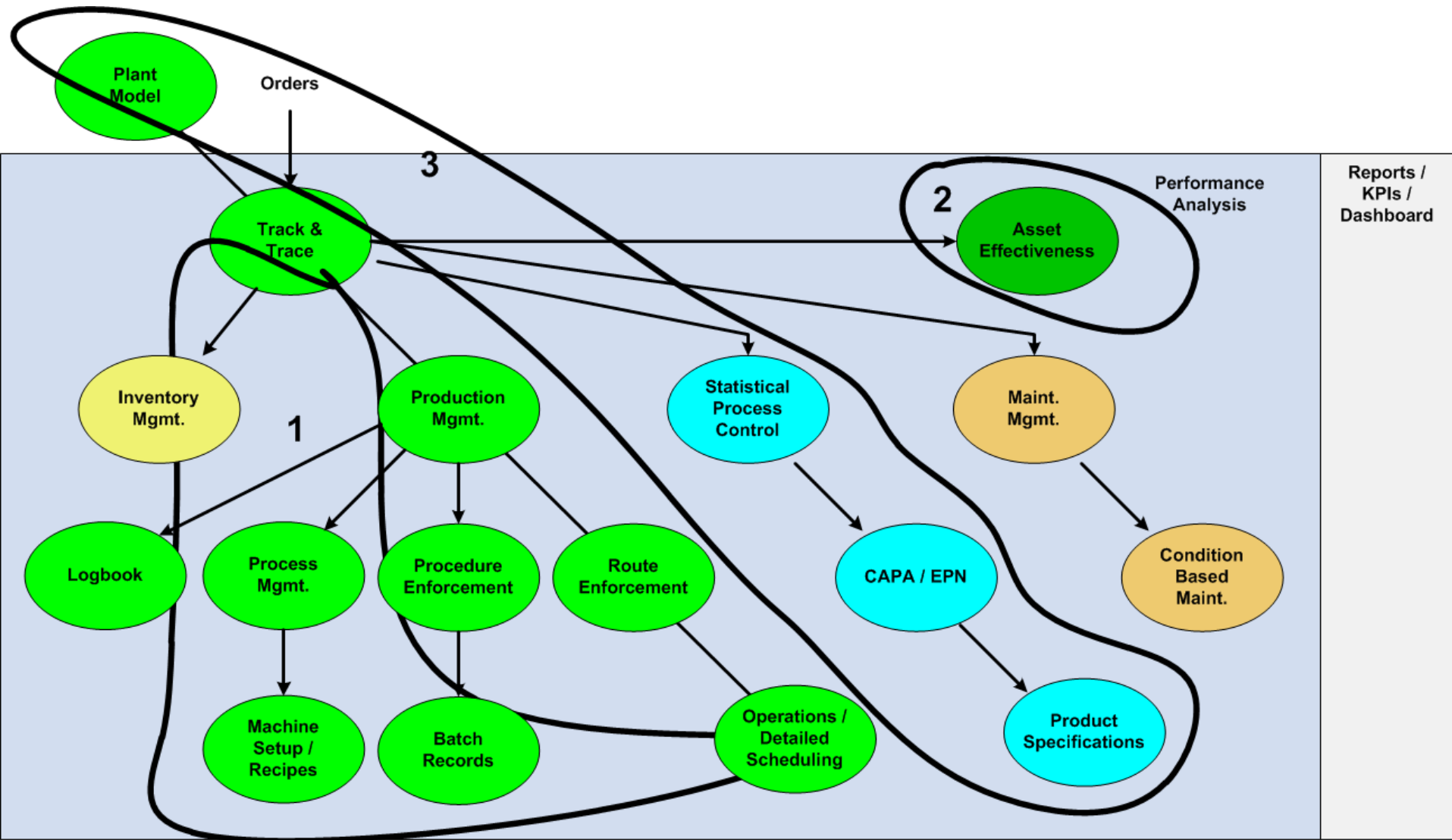
- In the **OLD NORMAL**, MES is barely above paper on the respect (i.e. funding) scale.

MOM – A Full Functioned View



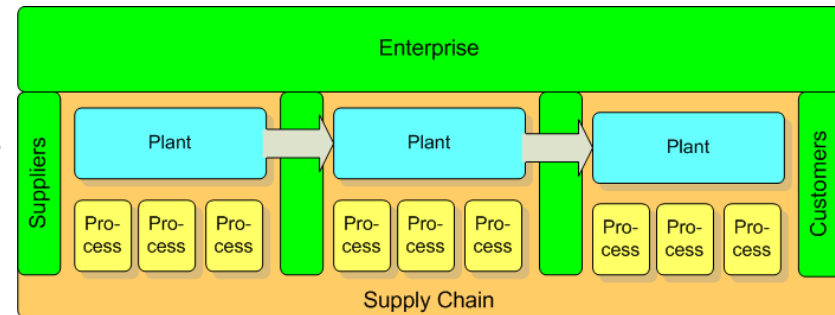
Manufacturing
Operations
Management
model from
ISA-95.00.01

Typical Manufacturing Application Deployment Waves



The New Normal

- Manufacturing Operations Management (MOM) is an integral part of an overall supply chain or enterprise manufacturing management system
- Outsourced manufacturing assets are integrated into the enterprise manufacturing management system; i.e. centrally managed
- Regulatory enforcement, batch record data collection, material management, and performance management are enabled by the same platform





MARKET TRENDS / DRIVERS

- Government regulations, incentives, market proximity and public sentiment drive multi-national manufacturers to locate assets within the same supply chain around the globe. These assets must operate in harmony.
- Manufacturing assets are managed on a global basis and must be predictable and responsive to shifts in the market (e.g. think flu vaccine).
- The new reality is that plant systems are no longer viewed as engineering or technical operations systems but are extensions of supply chain management.
- Product managers are looking for systems that enable faster tech transfer / new product introduction



- Brand liability outside of your control (e.g. CMO)
 - requires a new breed of application that has batch history across manufacturing sites.
- A central planning organization desires to have visibility of order status, asset performance and capacity in order to more effectively manage a global supply chain. Systems are not in place to promote this level of integration.
- Unique products coming into the market (e.g. autologous / personalized vaccines) which require traceability from pathology lab to therapist
- Government regulations with more strenuous traceability requirements for the supply chain (e.g. E-Pedigree)

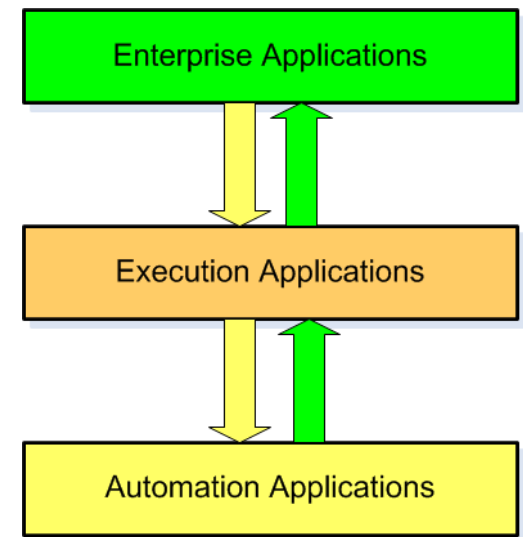




FUNCTIONAL IMPLICATIONS TO MES AND TO THE ERP INTERFACE

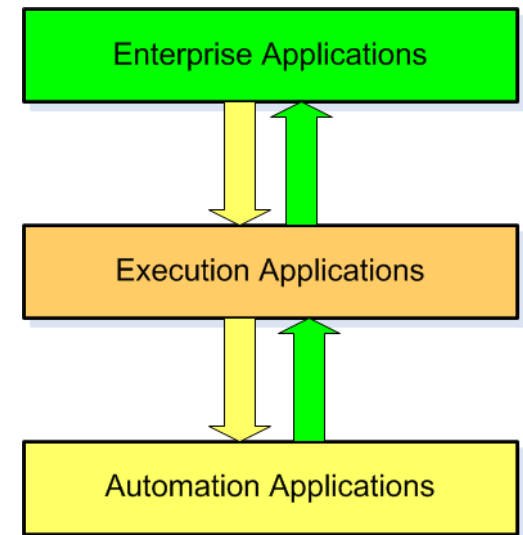
New Normal Requirements – Materials Management

- Tighter MES to WMS Integration
- Material management + material enforcement
- Anticipate movements based on schedule, current batch, current rate of consumption, etc.
- Automated material transport orders
- Enabled via RFID
- Tighter more timely synchronization of material status (i.e. system of record is typically ERP)



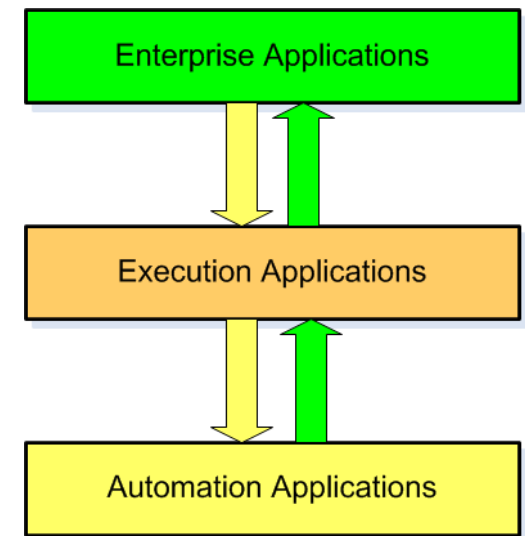
New Normal Requirements – (Asset) Performance Management

- Execution and performance management are tightly integrated (e.g. operational efficiency data is collected directly from the execution system).
- Classic lean / demand driven concepts are designed into the regulatory enforcement system (e.g. concepts like takt time, work sequence and non-variable work) to smooth out production variation and are used to drive improvements without compromising quality.
- Asset status (offline, etc.) is measured in real-time feeds into standard metric calcs.
- Standard metrics are rolled into KPIs / Dashboards and are aggregated to multiple levels to drive near-realtime responses to supply chain variations.



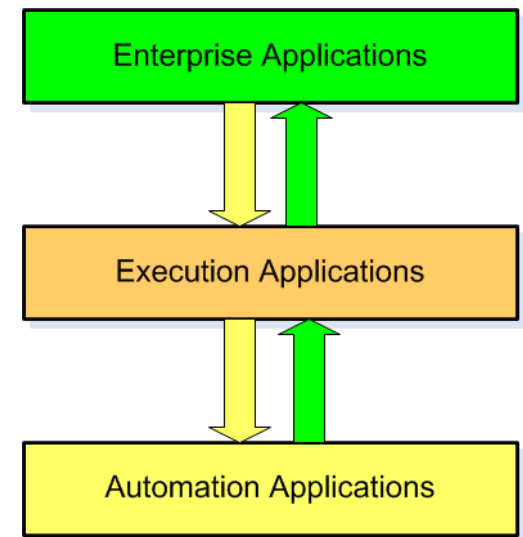
New Normal Requirements – Integrated Quality Management

- Product and process specifications are managed globally and enforced at the MES level.
- This includes material recipes, equipment setup parameters, product quality specifications, etc.
- Process and equipment setup is coordinated and confirmed through the MES
- CPP and CQA excursions are monitored and alarmed in real-time.
- In process quality sample frequency is escalated based on excursions in order to accurately establish deviation boundaries.
- Training record systems are integrated with the execution system to ensure operator qualifications for a particular operation.



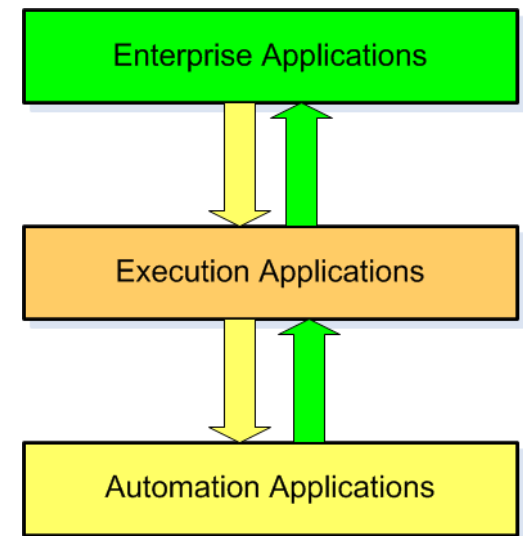
New Normal Requirements – Work-In-Progress

- Batch / lot / device status is tracked in real-time and synchronized with the business system (e.g. ISA95 – Production Performance messages).
- A more granular manufacturing model in ERP requires more feedback (e.g. inventory count points).
- Actual consumed materials are measured and reported at the point of use vs. back flushing for more accurate feedback and accounting.
- Material status is checked prior to delivery to the manufacturing suite or prior to consumption.



New Normal Requirements – Capacity Planning / Scheduling

- Actual KPIs are used to drive capacity planning and scheduling.
- Asset status (offline, etc.) is measured in real-time and synchronized with planning and scheduling systems. In some cases reactive scheduling may be employed when interruptions occur
- Detailed schedules are planned (or monitored) centrally to ensure optimum utilization of assets

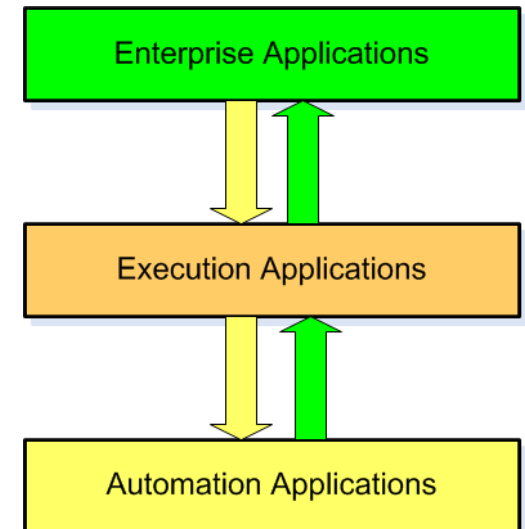




ENABLING TECHNOLOGIES

Five Integration Enabling Technologies

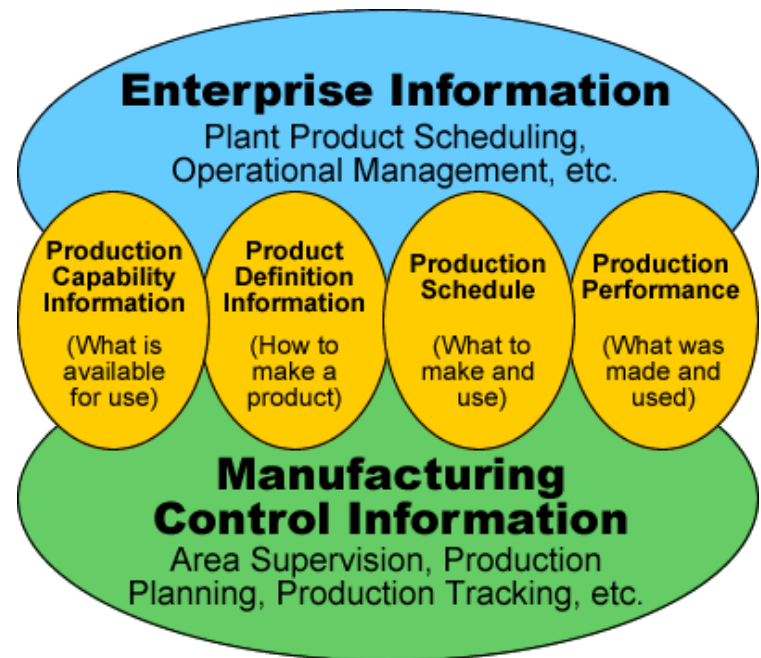
- ISA-95 B2MML
- RFID
- Real-time BPM / Workflow
- Open O&M Information Service Bus (ISB) - Beta
- Open O&M Common Interoperability Register (CIR) - Beta



Technology #1 - ISA-95 B2MML

The World Batch Forum (WBF) has published XML schemas based on the S95 Model - B2MML (Business to Manufacturing Markup “Hypertext” Language)

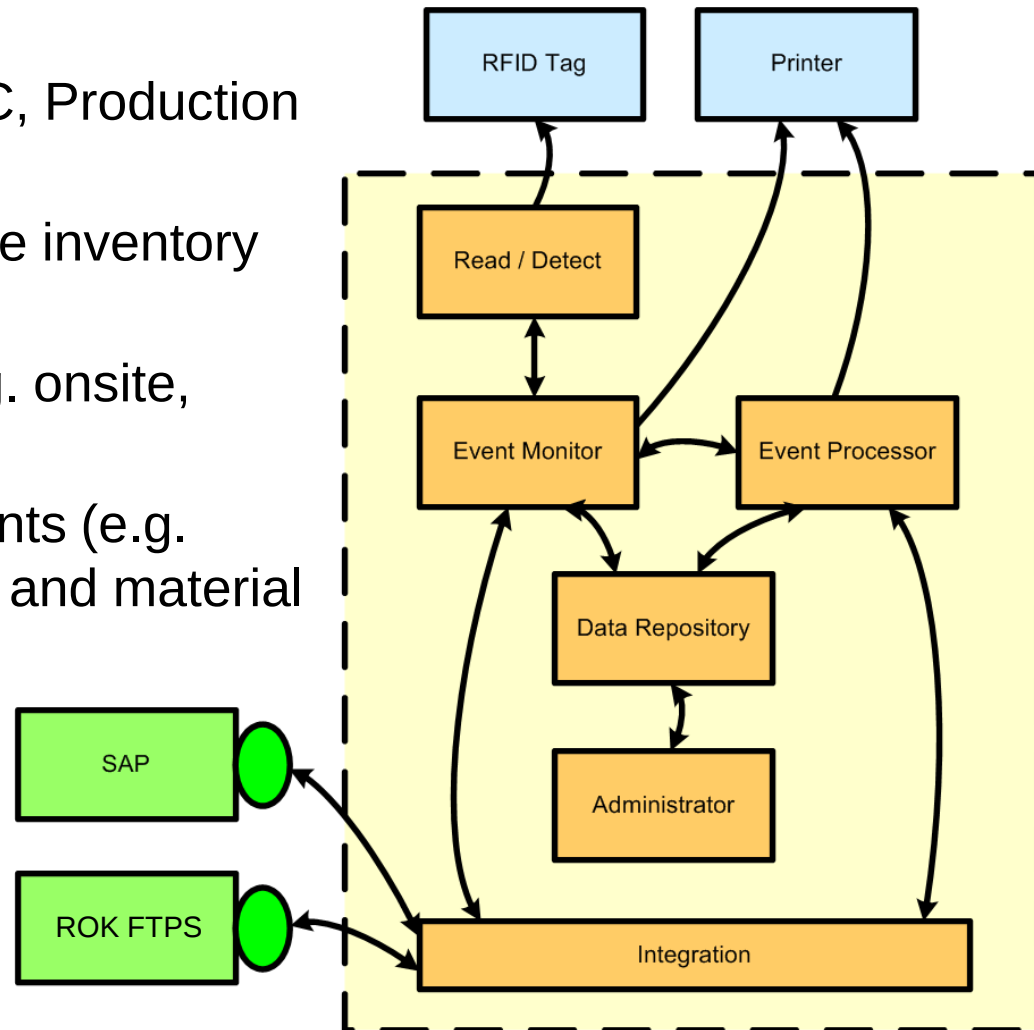
- B2MML-V0401-Common.xls
- B2MML-V0401-Personnel.xls
- B2MML-V0401-Equipment.xls
- B2MML-V0401-Material.xls
- B2MML-V0401-Maintenance.xls
- B2MML-V0401-ProcessSegment.xls
- B2MML-V0401-ProductionDefinition.xls
- B2MML-V0401-ProductionCapability.xls
- B2MML-V0401-ProductionPerformance.xls
- B2MML-V0401-ProductionSchedule.xls



Technology #2 – RFID

Material Tracking Examples:

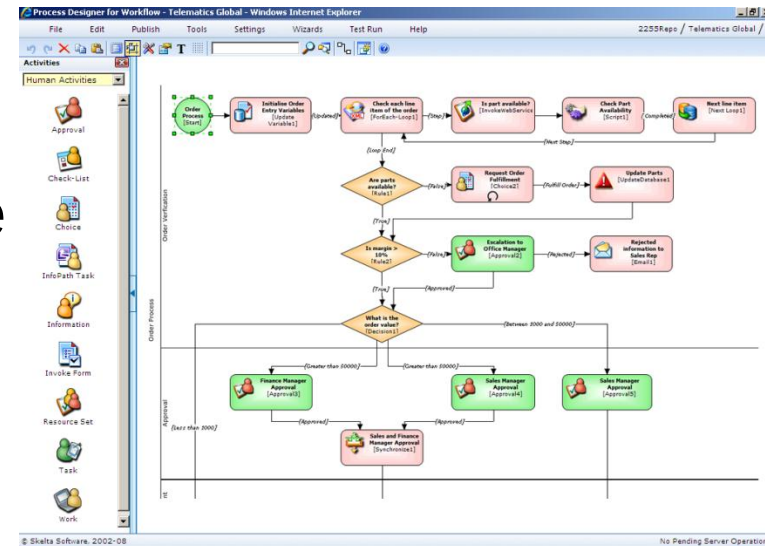
- Maintain asset status (e.g. IBC, Production equipment, etc.)
- Maintain WIP / production suite inventory levels
- Maintain personnel status (e.g. onsite, location, etc.)
- Determine material requirements (e.g. based on order, consumption, and material on hand by location, etc.)
- Initiate / Close Transfer Order
- Goods Issue
- Error Messaging
- Personnel ingress / egress



Technology #3 – Real-time BPM / Workflow



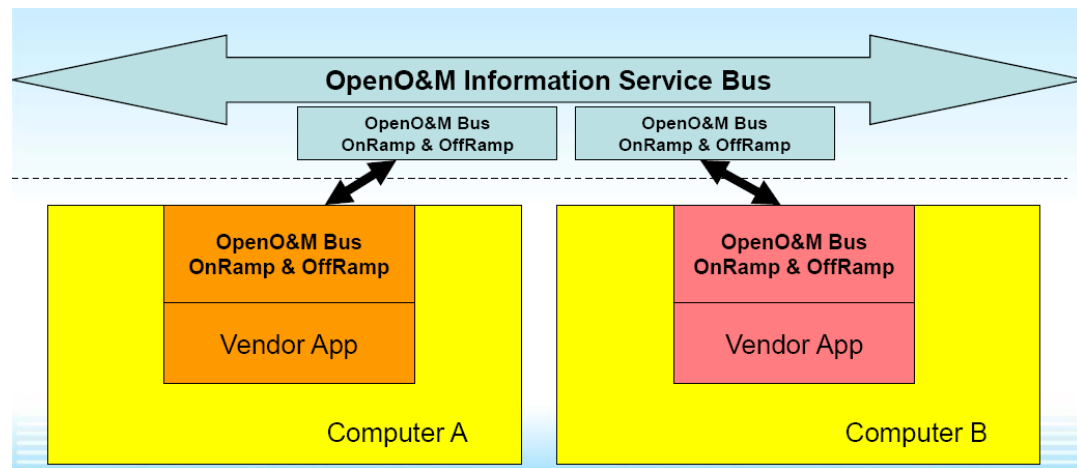
- Composite applications built on a common, distributable event-driven platform
- Event-driven manufacturing operations management software
- Orchestrated response to real-time factory events.
- Features include
 - real-time data collection, contextualization and analysis,
 - systems integration,
 - and critical event detection and response



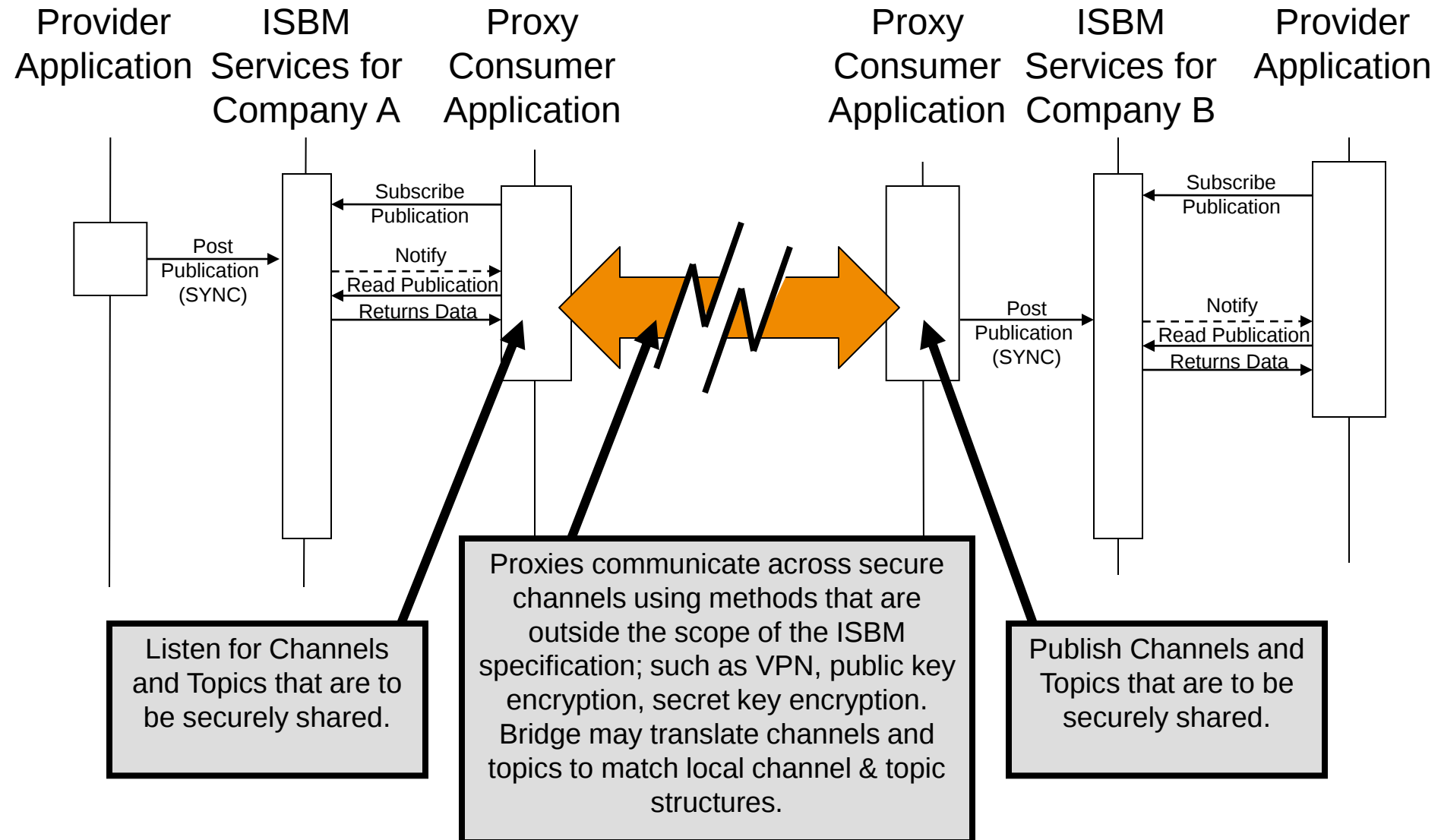
Technology #4 – Information Service Bus (ISB)



- A single source of shared information,
- A single location for discovering application services, and a
- Single destination for using services.
- Five elements of a ISB;
 - a data transfer element,
 - a service discovery element,
 - a data transform element,
 - a transaction protocol element, and
 - a payload element.

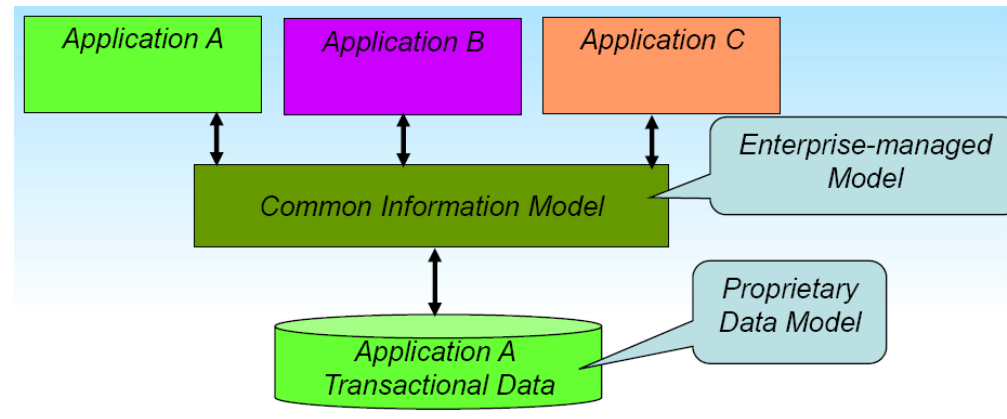


Cross Company Bridge



Technology #5 – Common Interoperability Register (CIR)

- Provides the “Yellow-Pages” lookup for all systems to locate an identical object in another system
- Glue to tie systems together which have different Identifiers for the exact same object but never had to talk “on-line” before
- Provides a globally-unique CIR Identifier (CIR Id) to link “local” object IDs





SUMMARY

- There's a 3rd wave of Life Sciences manufacturing solutions upon us while many are not half finished with 2nd wave.
- The 1st and 2nd waves of manufacturing systems was justified based on manufacturing efficiencies and productivity. The next wave of manufacturing systems will emphasize supply chain reliability and responsiveness, and product portfolio management (e.g. time to market).
- The 3rd wave is driven by the business and significant pressure will be brought to bare to implement it and implement it quickly. This is a move from line optimization (i.e. paper replacement or “paper on glass”) to enterprise optimization.
- MES is not just an operational system but is sliding onto the radar of supply chain & product managers.
- This pressure to implement has the potential to outstrip supply of knowledgeable resources who can lead the deployments.
- Performance management (or OEE or asset effectivity or asset management) increases in importance to drive consistency.

- The 3rd wave will be based on a general purpose MES engine adapted for EBR + WD to accommodate performance management or best-of-breed solutions collaborating via industry standards.
- Many existing systems are not architected to accommodate the new normal.
- Lessons learned from MES outside of Life Sciences are becoming important (e.g. F&B, CPG). Those industries have been attacking asset efficiency, utilization, material conversion, quality, etc. in order to manage product margins and overall product cost for a long time.
- Market trade winds and technological innovation are casting the integration of Supply Chain & MES / MOM in a different light.
- Congratulations, you are being invited to sit at the business round table. Beware of the implications.





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