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Standardized Traceability Ratings for Manufacturing

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Abstract
Traceability and process control are no longer requirements reserved for manufacturers in regulatory or specific market segments. Today, all manufacturers who aspire to achieve or to maintain a 'world class' status must deliver some degree of traceability. The PCB assembly industry lacked a common language regarding the nature of traceability or its levels. Nor has there been a means to benchmark such capability or to communicate its nature to customers or regulatory agencies in a common manner.

Recently, we, in collaboration with a leading supplier of dummy components and process testing kits, partnered together to offer an innovative kit designed to validate and benchmark the entire manufacturing process and provide the potential for rich product and process traceability detail. This new kit provides the physical materials and the procedural guide to determine a factory's traceability and control capability, and then rate the results in a formalized matrix. These ratings can be used to demonstrate capabilities, communicate to customers or auditors, or to provide a start point for manufacturers to improve their capabilities and track progress along the way.

This materials kit and ratings methodology aids manufacturers the demand-side of the market in the following ways:

- Benchmark Traceability and Control
  Test and validate three key elements of traceability; exercising quality manufacturing practices control mechanisms to assure process execution of these practices is proper even under high-change conditions, and the resultant reporting scope and depth that serve as evidence of the practices and controls performed. This approach of validating process control and visibility yields a comprehensive assessment of a factory's capabilities.

- Communicate Capabilities
  Using both the elements of the methodology and the metrics derived from an audit when it is applied, manufacturers have the means to convey to their customers or auditors their true traceability capability. In the past, this has been impossible without a common rating system or even a generalized agreement on the maximum range of what traceability entails. The purpose of this kit is to establish a common rating on the scale from simple traceability to world class capabilities. The scale can then be used to communicate a factory's capabilities in a uniform manner to management and external parties that require this information.

- Improve What is Measured
  The rating scale aids manufacturers who are continuously looking for ways to improve their factory operations. Through uniformed measurements, a road map can be developed to advance a plant's manufacturing processes, controls, and traceability. By measuring a factory's capabilities today, this kit aids in defining path to the future.

- Technical Basis
  Aegis' methods of rating traceability have been concurrently developed with, and adopted by, many of the leading manufacturers in the industry. The collective challenges and experiences of a customer base exceeding 1000 corporations on five continents have contributed to the scope of the methodology. Users of the method and kit consequently benefit from over seven years of definition and usage in factories all over the world to rate systems and processes against this scale.

Introduction
'Traceability' is one of the most common terms used in manufacturing but it lacks a common definition across any discrete manufacturing industry. According to ISO 8402, traceability is 'the ability to trace the history, application or location of an entity by means of recorded identifications. Tracing is the capability to identify the origin of a particular unit located within the supply chain by reference to records held upstream in the supply chain. Units are traced for purposes such as recall and complaints.' Even with this definition, however, it permits for a broad interpretation by the reader.

In most cases, clear traceability evidence and proof of one's traceability capabilities are difficult to communicate. Demands for heightened traceability from a manufacturing vertical, such as within the aerospace, automotive, defense, and medical

industries, are common for mission critical products. These industries offer their own guidelines, but even their respective standards often lack specific guidelines and contain terms 'as appropriate' or 'when appropriate' (ex: FDA CFR Part 820). For contract manufacturers, their OEM customers may apply greater demands upon them due to field quality issues and recalls, placing the manufacturer in a challenging position to identify possible root causes and isolating the affected products. Furthermore, OEMs that are evaluating potential EMS providers find it difficult to assess traceability capabilities in a truly uniform manner across their prospective suppliers. Therefore, the need exists to provide a traceability index to improve how a manufacturer communicates their capabilities beyond the physical factory.

Many manufacturers have addressed the traceability demands placed upon them as each individual item of data fulfillment is incurred as result of either their market demand or a customer demand of the moment. This never ending flow of individual data demands creates a greater long-term challenge for the manufacturer who tends to respond in a singular manner. For example, a manufacturer finds they are delivering products with invalid material. This issue is addressed with a point solution for materials verification. Later, this manufacturer finds excessive quality issues that are currently reported in an insufficient manner. This issue is addressed with a quality system. Again, the manufacturer finds problems due to insufficient functional testing. This issue is addressed with an in-house solution where the data is captured on a local database. While it appears this manufacturer is responding in a responsible manner, they actually have created a proliferation of point solutions across their reporting landscape. The result is isolated data sets with a never-ending requirement to have their IT departments stitch together for report fulfillment. A critical mass is eventually reached and the manufacturer finds themselves with a high overhead of IT reporting labor hours, system maintenance, system service contracts to multiple vendors and poor customer satisfaction because data fulfillment responsiveness is ultimately inadequate.

The solution to the above issues is for the manufacturer to evaluate their current traceability capabilities in a holistic manner. The manufacturer must consider all aspects that affect product traceability, from when it is introduced to the floor and to when it is ready for shipment. When this scope is determined, it's depth of data must also be considered. A common method for gauging a these capabilities provides an honest assessment for their site and is a means of comparison to other sites. With this method, a manufacturer can also measure their current state and roadmap a set of capabilities that lead to their ultimate state.

The methodology explained within this paper and the kit that enables its execution is built upon the following assumptions;

- The proper way to approach systems for traceability is to first fully explore the nature of traceability. To consider, accept, and define the maximum case of scope and depth of data fulfillment that may ever be requested by the market and/or customers. This 'maximum case' can in fact be defined because the scope of variable data emerging from a manufacturing process and embodied in the materials content of a product is finite.
- Next, the manufacturer must adopt a uniform methodology to audit their own manufacturing processes and product from the perspective of traceability, control, and data fulfillment.

Then, the manufacturer must agree upon a rating system in order to transform the audit of an admittedly complex information management issue into a simplified set of metrics suitable for intra-corporate and inter-corporate communication.

Defining the Total Equation of Traceability

The very term 'traceability' actually only describes the end but does not describe the means. The model described in this paper extends traceability to encompass not only the 'end' but the 'means'. To audit and rate traceability in a manner that could grant a manufacturer a high traceability metric when they only have a world-class method of reporting how poorly they builds product is not productive. They must have both the means to ensure a controlled process, and to prove they have such a process through data fulfillment. That is the complete equation of traceability which can be summed in this technical belief: ***Traceability is the natural byproduct of a properly controlled and monitored factory operation, not the goal in itself.***

The reason why a manufacturer may lack the ability to report traceability is due to the lack manufacturing practices and controls that yield resultant proof of the steps previously taken. For example, a manufacturer may be required to provide proof that a product did not withstand excessive temperatures while in process. In order to provide this proof, they first need equipment that is capable of logging this detail and a mechanism to ensure it meets the temperature criteria. Therefore, if traceability is a goal, the manufacturing practices and the controls ensuring theses practices to fulfill traceability requirements become the byproduct. Otherwise, traceability reports will possess incomplete, inaccurate, and undesirable detail.

Traceability can be categorized as two types: 'forward' and 'reverse' traceability. Forward traceability can also be known as a record of assembly and contain detail that serves as a certificate of conformance. It provides detail in respect to a given unit or assembly, and may reveal material content and its experience throughout the manufacturing process. It may identify a product's genealogy, from a packed carton number to a final electro-mechanical assembly serial number to its sub-assembly's serial numbers, and down to its contained circuit card assembly serial numbers. It may identify who, when, and where a

product was at a given time and what occurred at that time. Reverse traceability identifies units that may be commonly affected by sharing a common entity or experience. It may be used to identify the scope or impact of a possible recall or simply a means to identify where an item was used within multiple products. Examples of reverse traceability investigations include products that contain a common lot number for a given component, were processed by the same operator, or went through the same physical location during a given time period.

How traceability is addressed within an organization ranges from 'basic' to 'true' traceability solutions. Basic solutions resolve immediate needs and are typically point solutions. True traceability solutions consider both the immediate and long terms needs and broadly cover the manufacturing operations. These solutions can be viewed at hierarchical levels:

1. Point solutions are installed to obtain material content information from a physical location or data source.
2. Point solutions are installed to process variables from a physical location or data source.
3. Process-wide architecture is installed for obtaining material and process variable information from every step in the manufacturing flow.
4. Process-wide architecture that achieves the former level, but also implements physical electronic control to assure the process being traced is correct.

Rating Traceability: How the Metric is Obtained

The Traceability Ratings Guide considers use of basic to true traceability systems and with a means for scoring a given manufacturer's capabilities. It may be used for all discrete manufacturing processes where material is installed into a product. It generically covers both electronic and mechanical assembly processes, thereby offering a means to reflect a traceability score across an entire factory.

The ratings guide is contained within a Microsoft Excel workbook and offers backward compatibility with Office 97 products. A workbook format was selected as it does not require any proprietary software use/installation and offers both automated calculations and a means to organize information by worksheets. A 'Summary' worksheet returns color-coded scoring levels for a variety of manufacturing aspects and areas as seen in Figure 1.

Area	MANUFACTURING PRACTICES WITHIN THE FACTORY	CONTROLS ENSURING MANUFACTURING PRACTICES	REPORTING AND EVIDENCE OF ABOVE ACTIONS
General Tracking Methods	84.5	N/A	80.0
Revisions and Change Notices	N/A	98.8	80.0
Product WIP	89.5	94.4	100.0
Material Content	95.0	100.0	100.0
Inspection and Test	90.6	88.0	100.0

World Class Traceability Practices and Evidence	90-100
Excellent Traceability Practices and Evidence	80-89
Benchmark Traceability Practices and Evidence	70-79
Sub-Optimal Traceability Practices and Evidence	60-69
Traceability Practices Need Addressing	Below 69

Figure 1 – Traceability Ratings Guide 'Summary' Sheet

The Summary page includes an array of scores based on how the manufacturer completed the workbook. The cell rows cover the different manufacturing areas that contribute to overall traceability. The cell columns identify the various aspects to how traceability is measured. This page also serves as a dynamic table of contents, where clicking on the area entries or scores navigates the user to the desired section of the workbook.

The ratings guide does not provide a single final score as weighing criteria for each area against themselves is extremely arbitrary. Instead, the guide returns scores in report card form for each respective area. Scoring is classified into five colored

rank levels on a scale from 0 to 100. A 'benchmark' score is between 70 and 79 and is considered an average traceability capability. Areas that receive scores of 80 or higher are considered 'Excellent' to 'World Class'. Areas that receive scores below 70 are either 'Sub-Optimal or 'Need Addressing' and likely are contributing to operational issues regardless of the current traceability demands.

These areas where traceability is measured by the Guide are:

- General Tracking Methods – Identifies how traceability is performed within the manufacturing operations. This first area establishes how products are tracked, whether by time, job, or down to a serialized unit. It does not cover methodologies such as a Kanban or a pull system since a methodology may be employed to varying degrees and does not explicitly reveal manufacturing practices.
- Revisions and Change Notices – Identifies how assembly revisions are managed and approved for use for the manufacturing operations. It also identifies how process documentation (work instructions) and engineering change notices (ECO/ECN) are delivered to the manufacturing floor. It does not cover how revisions and ECOs are triggered and facilitated by an organization, but only how it ultimately affects use and notification on the manufacturing floor.
- Product WIP – Covers all product-travel related areas. Product WIP identifies how serial numbers are applied to the product (labels/direct marking) and how serialized products are introduced and tracked throughout the manufacturing process. It also covers related product attribute capture, such as for manual data collection of calibration and torque settings, genealogy capture for parent/child assemblies, and for packing a given assembly.
- Material Content – Covers all material related areas and identifies how material associated to a given product is verified during the manufacturing process. It covers bill of material content, tooling, chemicals, operator certifications, recipes, and any discrete entity that is sensitive to the build of a given product.
- Inspection and Test – Covers all inspection and test actions performed for a given product. It covers in-circuit and functional tests, human and automated inspection, and repair functions.

Ratings Guide Worksheet Layout Explained

Each scoring worksheet is laid out with a consistent structure. The criteria are presented in questionnaire form to permit the manufacturer or an independent party to intuitively supply an appropriate score. The criteria in each worksheet are organized by the following categories:

- Manufacturing Practices Performed Within The Factory – This category covers actions and steps taken by the manufacturer.
- Controls Ensuring Manufacturing Practices – This category covers how the above steps are controlled and ensure product is built to these practices.
- Reporting and Evidence of Above Actions – This category covers the actual traceability-related criteria for the above areas.

MANUFACTURING PRACTICES PERFORMED WITHIN THE FACTORY
CONTROLS ENSURING MANUFACTURING PRACTICES
REPORTING AND EVIDENCE OF ABOVE ACTIONS

Area / Capability	% of Method Used In Factory	Max. Value	Section Score	Section Weight	Weighted Score
MANUFACTURING PRACTICES PERFORMED WITHIN THE FACTORY					**89.5**
WIP Tracking					
Our factory automatically captures serial numbers at inline equipment throughout the build process where product WIP awareness is critical.	70%	100	70		
throughout the build process.	20%	100	20		
Our operators manually record serial numbers within an electronic WIP tracking system at physical locations throughout the build process.	10%	70	7		
Products serial numbers are not tracked throughout the build process	0%	0	0		
	100%		**97**	**20%**	**19.4**
CONTROLS ENSURING MANUFACTURING PRACTICES					**93.4**
Build Start Readiness					
Our factory utilizes an electronic WIP tracking system that requires the operator to acknowledge all preparation steps were completed prior to starting the build process.	90%	100	90		
Operators do not review preparation steps prior to starting the build process.	0%	0	0		
	90%		**90**	**10%**	**9**
Barcode Read Assurance					
Our factory utilizes hardware that prevents product traveling on conveyorized equipment to continue if the barcode is not successfully read.	100%	100	100		
Our factory does not utilize hardware that prevents product traveling on conveyorized equipment to continue if the barcode is not successfully read.	0%	0	0		
	100%		**100**	**15%**	**15**
REPORTING AND EVIDENCE OF ABOVE ACTIONS					**97.5**
Our factory is capable of readily producing a single report that details all of the above applicable	90%	25	22.5		
Our factory is capable of readily producing reports for each work cell that details all of the above applicable actions for a given serialized unit.	100%	20	20		
Our factory is capable of readily identifying all parent/child serial number relationships, from the sealed carton down to the lowest level child unit or units.	100%	25	25		
Our traceability reporting detail identifies the physical location where the above actions occurred.	100%	10	10		
Our traceability reporting detail identifies the operator that performed the actions at each location.	100%	10	10		
Our traceability reporting includes date and time detail for each action.	100%	10	10		
	Enter 0-100 for each cell above.		**97.5**	**100%**	**97.5**

Figure 2 – Traceability Ratings Guide 'Product WIP' Worksheet Excerpt (*not complete criteria*)

Worksheet Scoring Explained

Under each category, criteria are grouped by functions performed by the manufacturer. In Figure 2, under the 'Controls Ensuring Manufacturing Practices', the criteria is grouped by 'Build Start Readiness' and 'Barcode Read Assurance'. The manufacturer then works across the row and supplies a percentage value for each entry within the grouping to determine how often it is performed in their operations. In most cases an overall grouping percentage should equal 100%. The workbook automates this function by guiding the user with color-coded cues when the percentage falls below 100% (as seen under Build Start Readiness). In other cases, as seen under the 'Reporting and Evidence of Above Actions', the user is instructed to supply a range of 0-100% for every row. The remaining columns for each cell are automated and write-protected and are as follows:

- 'Max. Value' – Specifies the maximum possible value for a given entry. In most cases the value varies from 0 to 100. In other cases, as seen under the 'Reporting and Evidence of Above Actions', the values found in a group sum up to 100.
- Section Score – Product of '% Method Used In Factory' and 'Max Value' cells. The resultant score is affected by the percentage supplied by the manufacturer.
- Section Weight – A given category, such as 'Controls Ensuring Manufacturing Practices' and may contain several grouping. Each grouping is weighted in respect to the entire category and collectively equal 100%. In Figure 2, 'Build Start Readiness' has 10% weighting within the Controls Ensuring Manufacturing Practices. Only a portion of the entire Product WIP worksheet is presented and is why the shown groupings do not total 100%.
- Weighted Score – Product of grouping's 'Section Score' and 'Section Weight'. The category's total score is also displayed in this column in the category's title row. In Figure 2, 'Build Start Readiness' received a section score of 9 and the 'Controls Ensuring Manufacturing Practices' received a category score of 93.4. The category scores are also found on the 'Summary' sheet.

Uses of a Common Ratings System

While the spirit of traceability provides tangible proof against a manufactured product, evidence of a given manufacturer's traceability potential is not easy. It is possible (and common) for two different manufacturing plants of similar size to own similar production assets. However, the differences are found with the manufacturing practices employed, control and logging options purchased for their equipment, and the systems used to support their operations. The ratings guide reveals these differences and permits an independent reviewer to discern the true difference between what appears to be similar operations on the surface. With a scoring system the ratings guide can also support a means to measure the following:

- Rate factories across an enterprise – A corporation can assess the capabilities found at each plant, rank each site, and promote the locations in the best position to support traceability-sensitive manufacturing.
- Rate lines within a factory – A single-site manufacturer can individually measure the varying capabilities found in their respective production lines or areas by creating a workbook for each of these areas. For contract manufacturers, they can present advanced capabilities for lines dedicated to traceability-sensitive manufacturing and promote these capabilities to potential customers.
- Program management – With knowledge of their company's manufacturing capabilities, program managers can make intelligent decisions to where products are best run within their operations and make these assignments more effectively.
- Sales executives - With knowledge of their company's manufacturing capabilities, their sales team can communicate traceability capabilities accurately and intelligently.
- Quantify improvement – Since traceability capabilities can now be measured, they can now be managed. The guide can reveals areas that require addressing, but do it in a manner that allows the manufacturer to consider all traceability aspects and forge a traceability roadmap.
- Costing – The scores derived by the ratings guide can correlate to a cost of assets and systems necessary to support a current and future state. Modifying a future state's requirements (and score) may affect the cost to achieve traceability.

Conclusion

Improving traceability capabilities is an important driver for most manufacturers today. Until now it has been impossible to quantify traceability across manufacturing locations and industries. A common ratings guide, independent of the manufacturer provides a normalized gauge, and therefore a common language, to how traceability is communicated. It is not intended to serve as an indictment of one manufacturer against another, but instead to establish a way to factor traceability with equally weighted criteria.