TRACEABILITY

Sourcing the Data

a Critical Challenge

RADLEY
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TRACEABILITY

Sourcing the Data

— a Critical Challenge

It's no secret that more and more companies across multiple industries are being challenged by the need to track and completely trace products they produce or materials they handle. Driven by the FDA and regulations such as FSMA (Food safety Modernization Act) and HACCP in the food and beverage industry, hazardous material requirements driven by the EPA and DOT, worker safety driven by OSHA, automotive safety requirements from NHTSA, HIBC for healthcare, etc., organizations are under constant pressure to adapt and keep up. Identifying what data attributes are required to be compliant is tough enough, but added to that challenge is being able to determine where, when and how often the data is collected and how granular it needs to be.

Business solutions, including traceability systems need timely and accurate data to be meaningful and responsive. These solutions utilize modern BI (business intelligence) reporting tools and dashboards to provide a historical view of data and the ability to quickly and perform queries. These tools also help visualize normal day to day operations. More importantly, they help to highlight exception events which trigger immediate notification and predetermined courses of action when exceptions occur. But if the core data is not current, is missing or worse, is inaccurate the value of the solution is diminished and non-compliant situations or breaks in the traceability chain can occur.

Determining Your Data Needs

"...understand the minimum data needed to be compliant to regulations driving your requirements."

A good place to start when determining what data you need is to understand the minimum to be compliant to regulations driving your requirements. The identification and collection of this data alone can be a difficult task. It may require gathering traceability record data from suppliers on incoming materials and appending that to the beginning of your internal traceability custody record. Transportation data may be needed such as trailer temperature, transit time, product condition, container information, etc. Certainly there will be a need for incoming lot and or serial number details,

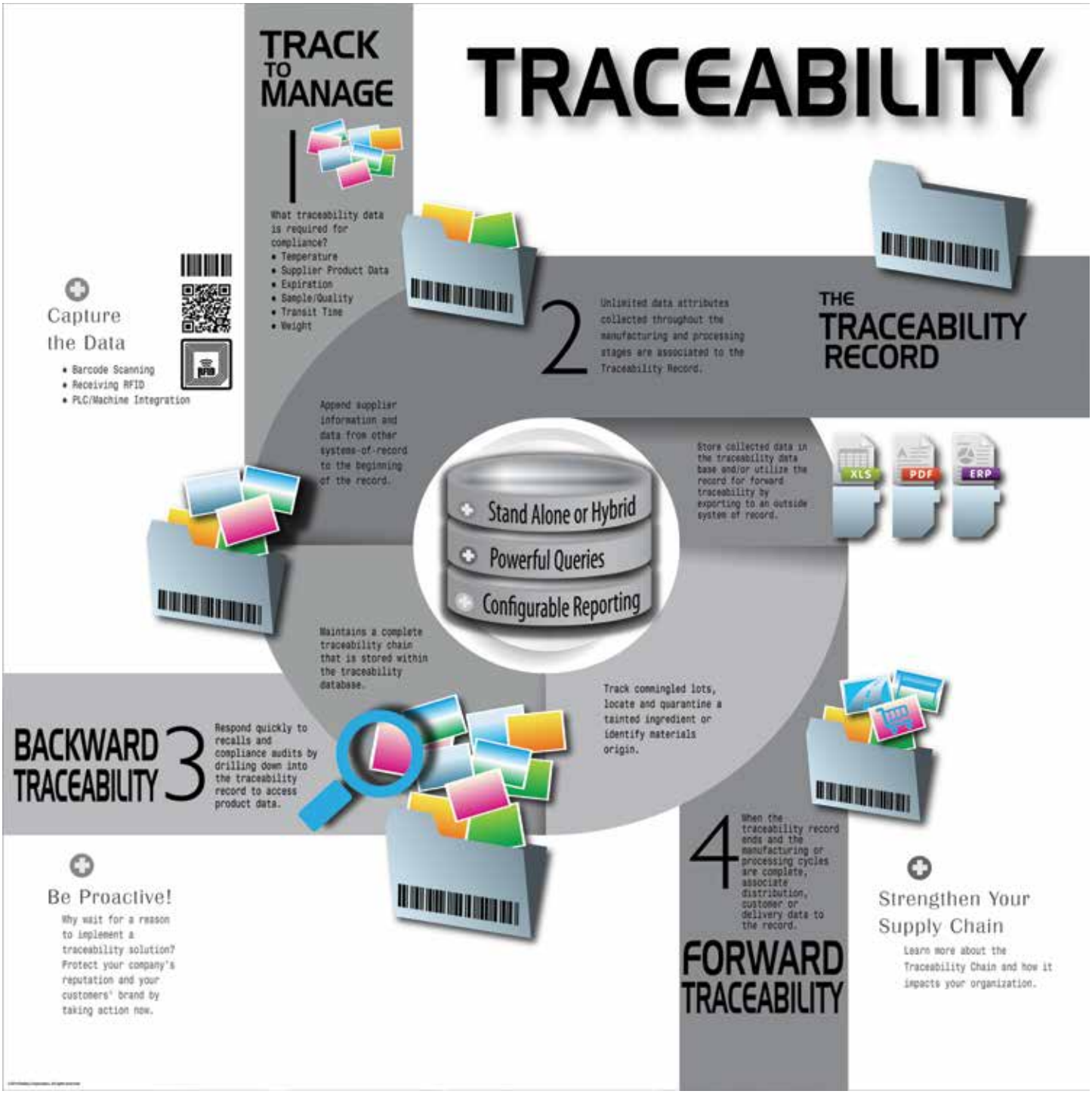
production dates, expiration dates and other basic information. Once the traceability record begins within the enterprise; the type of the product or material being produced, the critical nature of the supplies being utilized and the processes they go through will help determine the granularity of the data required for traceability purposes. You should also consider other data you could collect to both further mitigate quality concerns and enhance response time, in addition to more data about operations that can be used to better measure performance and improve efficiencies.

Take a Two-dimensional View

One way to begin outlining your internal traceability record requirements is to take a two dimensional view of your organization. Start with the output side of your processes. Select one of your finished products and determine what data attributes would be required in order to track it back through all its inputs if there were quality issues. The inputs would include all of the supplies, raw materials or ingredients (by lot or serial number at a minimum), each process or operation such as measuring, weighing, mixing, heating, cooling, drying, aging, etc. Also included would be each piece of equipment or machinery, even specific tooling that was used to produce that particular product. QA benchmark points such as each worker that that handled the product, each location and duration of storage, even if temporary and any packaging or repackaging. This type of analysis will need to be done for all of your products that require traceability.

The next view is from the raw material or supply side of your processes. Evaluate your suppliers, as each raw material or ingredient input needs to be reviewed to determine the level of risk it represents for potential quality issues. This may mean a more in-depth review of the supplier(s) of this material or ingredient to determine if their traceability processes and attribute granularity meets your needs. Critical suppliers should be able to provide a traceability record by lot or serial number with the appropriate associated data attributes such as production dates, best by dates, mill numbers, etc. that your organization can append to or be made part of your own ongoing traceability record; that you can also pass on to your customers or partners.

Look forward through all of the processes that ingredients, materials or supplies may potentially go through to create products or sub-products. While similar to the view from a finished product back through the processes to identi-

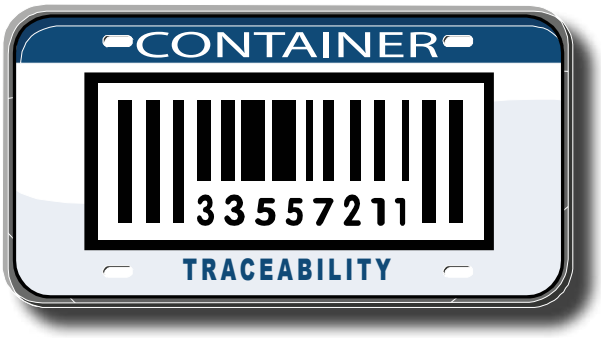


fy traceability data attributes, there are some significant nuances. What you are looking to identify here are all the possible end products a given supply or ingredient may be used in and how many possible routes it may take through various production lines or processes including machinery, automated equipment and handling points. Perhaps a portion of a raw material lot is taken and mixed with other partial material lots to create a sub product or sub component. This sub product becomes its own lot (or serial number) and then goes back into the supply inventory to be partially consumed as needed for other finished product production or maybe even more sub products depending upon the complexity and diversity of your products. Armed with this

information you now can begin to get an idea of not only what data you need and how often you need it, but where to collect it. If you are running a modern ERP system, much of this information may be right at your fingertips. Many of these process transaction points were likely identified during the solution mapping phase of your ERP implementation. You have a great start, as you are most likely capturing at least some of the needed attributes for your traceability record.

Structuring the Data

A significant impact on the type and volume of data required is the application, or system of record that will store the traceability record. Many organizations have implemented a traceability solution or process ERP system only to find they need to hire or redirect staff for manual data entry into these systems in order to meet ongoing transactional data requirements driven by the solution. Implementing barcode scanners and label printers (or RFID tags and interrogators) to scan/read the data automatically into the target application is a good first step. But if it isn't implemented efficiently, it may not be enough to source all of the data attributes required for compliance purposes in addition to the ongoing transactional data needed for the application. In fact, it may mean more scanning and printing hardware, more floor level workflows and scan points than needed and therefore more workers scanning than is necessary. This is where a well thought out data structure design can significantly increase efficiency and reduce the number of scans (or reads) required to collect the data that your analysis has determined is needed.



A flexible, dynamic data structure that maintains unlimited levels of parent/child relationships, including status and history should be part of any solution you choose to implement. It should include the ability to add unlimited data attributes at any point in the process without being constrained by database schema. This is important as it significantly limits the amount of customization to the solution to accommodate changing data attribute requirements. A label (or tag) serial number often called a "license plate" can be created for an individual item and all associated attributes at any point in your process such as lot, container, bin, tote, rack, etc.

"Many organizations have implemented a traceability solution or process ERP system only to find they need to hire or redirect staff for data entry into these systems to meet ongoing transactional data requirements driven by the solution."

When the label is created, the attributes are assigned to that label in the database. Combined with automated data collection, a single scan of the "license plate" will update your system(s) with the transaction performed as well as the data of

the master container (parent), the data of all sub containers (child), all of the associated items within any sub containers and all of the data attributes of each master, child, items, lots etc. It is critical that a history is maintained which logs any changes to a license plate as items or sub containers are added to or removed from master containers. This type of a data structure can significantly reduce the amount of workflows, scan points and scans required to collect the traceability data you need.

Collecting the Data

The collection of your data is another important consideration for your traceability requirements and your overall operational needs as well. Data needs to be collected and validated real-time as events occur and materials move through your processes. The value of your data is directly related to its freshness. The older it is when it is collected, the less meaningful it is to decision making and the less responsive an organization will be to exceptions in their processes. Comprehensive traceability data can be derived from many different sources within an organization. Most commonly, bar code labels are used to grab basic data about materials as they move through the facility. These are much more efficient when used with a data structure similar to that described previously. Just about anything can be barcoded with today's rugged labels, adhesives and diverse scanning technology. RFID is a great technology to supplement bar codes under the right circumstances, but physical limitations of the technology make RFID-only solutions very challenging and potentially much more costly especially in process environments.

Comprehensive traceability data can be derived from many different sources within an organization.

Integrating your traceability solution to networked equipment and other existing databases is a great way to supplement your data while also reducing the labor needed to collect it. Communicating with PLC's (programmable logic controllers) that front end machinery is very common and you may already be doing it for other purposes. OPC (object linking and embedding for process control) is a standard that has greatly simplified the process of communicating with PLC enabled equipment. One of the most common integrations in a process environment is scale or measuring equipment communications. The precise weight or volume of ingredients and the history of those processes can be critical for your traceability record.

Some of the traceability data you need may already be available in a solution database used for other purposes such as QA, asset maintenance, machine monitoring and OEE, production reporting, etc. Merging this data or the specific subset needed for traceability to the traceability record should be part of your solution. Another option is to integrate the collection of data for other systems into your traceability process. This allows multiple systems to be updated from a single scan point or workflow resulting in greater labor efficiencies.

Solution Architecture Considerations

There are many options when it comes to selecting a solution to help meet your traceability needs. The size of your organization will help drive your solution architecture requirements as it relates to functionality breadth and budget. You may already have a system in place such as an ERP, that can help get you get started. Here are a few basic architecture options:

ERP or Other Multi-purpose Business Management Software

This type of solution is usually a suite of integrated applications on a common database that is implemented across functional areas of the enterprise. Large, multi-location organizations almost always have a solution of this type. Versions of these solutions developed for process based manufacturers tend to have a good basis to support traceability requirements with at least some of the functionality described above. Most ERP type solutions support lot and serial tracking and for many users this is enough for basic traceability. However, for those faced with more complex data attribute tracking requirements it most often means customizing the ERP system, database and data collection network for the initial requirements. This customization effort and cost continues to grow for any additional requirements that come up as new customers, products or market segments are added to the mix and are magnified during software version upgrades.

Stand-alone Traceability Solution

A pure traceability solution that helps organize the data with a flexible parent/child relationship structures. This type of solution should have features such as license plating and or containerization to support aggregation and organization of data to reduce the amount of labor workflows or scan points and material flows through the various internal material utilization processes. Another key capability of this type of solution is the ability dynamically configure or add an unlimited amount of various data attribute types that can be collected and maintained to support the requirements. The traceability solution should provide reporting tools and dashboards to monitor performance. A critical component of the solution

A critical component of the solution is alert/notification capabilities whereby operators or management are alerted real-time to exception events or conditions.

is alert/notification capabilities whereby operators or management are alerted real-time to exception events or conditions. A stand-alone solution will inherently have the ability to collect data via bar code or RFID technology, as well as the ability to pull data from machinery, cooking/mixing equipment, scales, sensor networks, etc. These types of solutions are usually used by small to mid-size companies.

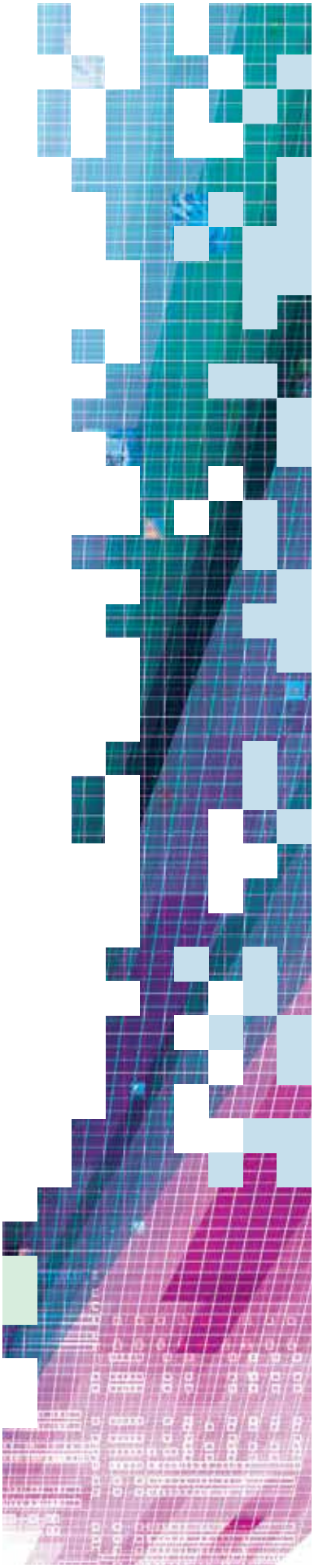
Hybrid Solution

This involves front ending an ERP or multi-purpose business system with a complimentary traceability/data collection solution. A hybrid solution combines the inherent features of both systems with the added benefit of combining disparate

transactional workflows to allow additional data to be collected at a single scan point; usually a transactional milestone in the ERP system or a product handling point. From each scan point the solution then updates the ERP record, the traceability record and any other business systems if necessary. The combined solution also runs on the same database to ease reporting for BI purposes.

Conclusion

Your organizations industry, customer requirements, products, processes and systems will drive your data requirements. A well designed solution will help you be flexible with how you collect it, where you collect it, how the data will be structured and how it will be integrated to your various other systems. It provides you a means to trace your products or sub products either forward or backwards from any point in your process and will allow you to share your traceability record with your customers and partners. Developing a well thought out and strategic traceability plan vs. reacting to specific requirements tactically as they arise will allow you to build a more dynamic and sustainable business system. This approach will enable your organization to minimize problem impact, enhance your ability to simulate as well as accommodate market segment growth and diversification while mitigating risk with the added benefit of a much lower long term cost of ownership.



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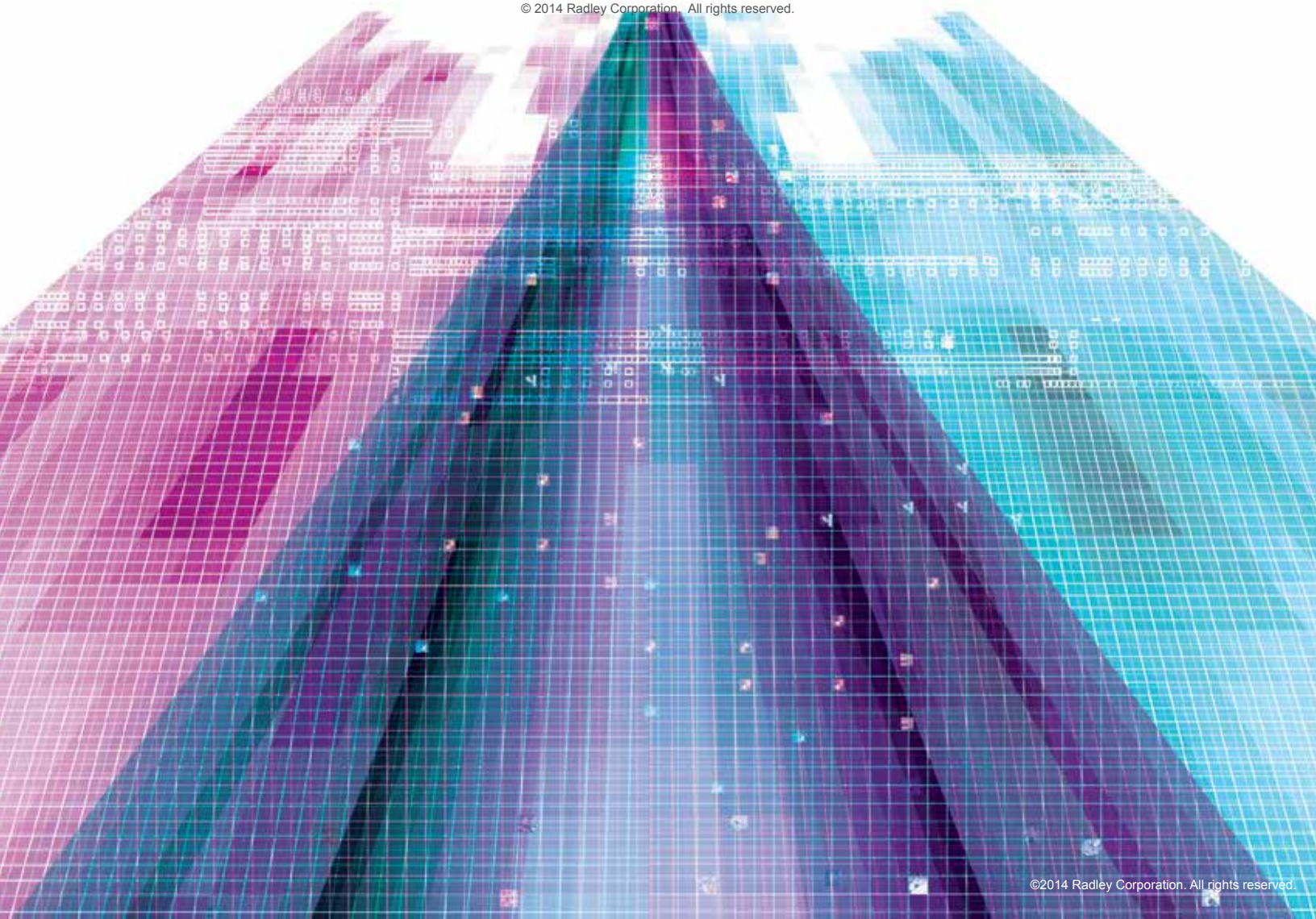

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