Tracking and Tracing on an ISA S88 foundation

Ing. Geert Vanhove
Product Manager proCX
Compex N.V.
Halsesteenweg 31
Ninove, Belgium, B-9402
Tel (+32) 54 312 694
Fax (+32) 54 324 660
E-mail geert.vanhove@compex.be
http://www.compex-group.com

KEY WORDS
Tracking, Tracing, Traceability, Batch management, Recipe, S88, SP95, MES

ABSTRACT
From which supplier ingredient lots did we compose this batch? Which batches did this pallet feed? Which batches ran after it? What’s the effect of this badly performing unit on previous operations? What’s the correlation between…?

These are not easy questions, too often left without an answer. In many cases we have to rely on a combination of the operator’s memory, some paper log sheets and a variety of electronic data sources.

With the introduction of the ISA S88.01 standard in 1995 and the work of the SP95 committee, process industries finally receives a structured framework that extends its advantages beyond the pure process control aspects. By applying the standard, we have a basis for building in traceability as an intrinsic function of the production control system.

We will focus on topics like material flow control, the process inventory, integrating quality control and non-conformity checking in the batch recipe and building product genealogy. During the presentation we will explain the methodology behind this and how leading enterprises have already successfully applied it.
1.1 What is tracking and tracing?

We all heard the typical horror stories of market recall: needles in baby-food, CIP chemicals in beer bottles or –more recently- pharmaceutical supplies in the wrong ampoules, dioxine in fat and the Coca-Cola recall. The message obviously is to avoid it, but in this exceptional case a manufacturer is confronted with it, it is surely important to identify with absolute certainty the exact cause and – consequently- determine the involved lot numbers and their current locations for the recall. The key is passing the right message fast to the public and the government. So far the stereotype example. In 99.9% of the cases, analyzing the production activity is situated in less harmful situations with the objective of improving quality, efficiency and throughput and decreasing off-spec product quantities.

This implies that you can reconstruct the exact circumstances under which the production activity took place and in order to do that you need information. Since the questions and problems are mostly unpredictable, we are not talking about a few data points. We are talking about lots of them of different kinds, sources and meaning.

To find your way in this data-jungle is in fact what tracking and tracing embraces and if you were already confronted with the theme you will know that it really is a jungle. The challenge is to accomplish a methodology that eases the job and in the first place this sets the requirements to the data straight:

- Reliable information
- Clear and unambiguous relations between different types of information
- Information that is sufficiently complete for reconstructing the circumstances (so reducing the assumption level)
- A clear scope where the information applies.

The latter requirement indicates that tracking and tracing has a role over the entire supply chain. In practice this translates in browsing different sources of information including production control systems (MES), supply chain management systems (SCM), Enterprise Resources Planning (ERP) systems, warehouse management systems (WMS) and distribution management systems (DRP). In this paper we will focus on tracking and tracing within the walls of the production facility. This is the place where ingredients explode in a range of outgoing products, so obviously also the place where the risk of losing the track is relatively high.

To identify the kinds of information we are envisioning, we best look at the activity that induces them. The activity of controlling a production process means managing:

- Equipment / tools
- Materials / parts / product
- Work instructions / procedures / recipes
- Labor
- Facilities
It is the intention of this paper to relate this to the S88-01 concepts. Therefore we will focus on it from this perspective, which includes that we will discuss the tracking and tracing theme for batch process industries.

1.2 The information model as a foundation

1.2.1 Equipment

The equipment model described in S88.01 forms the appropriate backbone for equipment related information. The process control function—as defined in S88.01- takes care of the equipment information.

In this context we only focus on information that is purely and directly related to the equipment itself and not to the activity (phases) that uses the equipment as a result of the procedural control. This includes:

- Process measurements (trends, SPC)
- Equipment alarms
- Operator interactions (e.g. manual process actions)
- Operator comment

All types are uniquely related to time and the equipment identification (e.g. tag name).

1.2.2 Materials

Materials should be interpreted in a broad sense:

- Ingredients, intermediate, semi-finished and finished products
- Recipients, excipients (containers, packaging materials, bins)
- Others like air-filters, ultra-filters used for a particular batch.

It is important to make the distinction between identifying the material itself and identifying the actual instances of that material. The latter are often referred to as material lots. Because we want to approach it in a more generic way, we define this as a traceable material having a traceable material ID (TraM ID). The different TraM IDs with their respective quantity will define the current process inventory of the associated material ID. Some examples:

Material ID: M4453 Description: Plastic bin for non-active ingredients

<table>
<thead>
<tr>
<th>TraM IDs</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>T10021</td>
<td>1 pce</td>
</tr>
<tr>
<td>T10022</td>
<td>1 pce</td>
</tr>
<tr>
<td>T10023</td>
<td>1 pce</td>
</tr>
</tbody>
</table>

Material ID: M3265 Description: Milk powder
TraM IDs   T20010   10.000 kg  
           T20012   30.000 kg  
           T20054   25.000 kg  

Most systems tend to bind a lot of information to the TraM ID (like quality test information, links to batches, etc). It is our experience that this makes the tracking & tracing activity difficult and ambiguous. Traceable materials move in the process, often in portions and they disappear in batches. It is therefore better to associate information to traceable materials through the production activity that induces it and register only the path the material follows during these activities. With respect to tracking and tracing, this results in the inventory transaction log, which contains basically:

Transaction type: CHECK-IN, CHECK-OUT, MOVE, TRANSFORM
Transaction date and time
Source:       TraM ID
              Material ID
              Unit (equipment, location)
              Quantity / Units of measurement
              Minimal set of attributes (e.g. status: clean, dirty, released)
Destination:  TraM ID
              Material ID
              Unit (equipment, location)
              Quantity / Units of measurement
              Minimal set of attributes (e.g. status: clean, dirty, released)

Check-in transactions occur where new material lots are received. They get a destination in the production facility (source is blank).
Check-out transaction occur where produced materials or waste leave the production facility (destination is blank).
Move transactions register that a TraM ID or a portion of it moves to another location.
Transform transactions register that a TraM ID transforms to another Tram ID, which is of course referring to batch inputs and outputs. Also the material ID changes with this transaction.

If we succeed in accurately logging this information, we can track a material from the entrance to the exit of the production and back. In this way you obtain what is commonly called product genealogy. How we can bind information to a particular node in the genealogy tree is described in the topic on production methods.

1.2.3 Labor

Depending on the type of industry, tracking information on labor is stressed in a different way. In regulated industry (pharmaceuticals, biotech,…) it is definitely important to register who-did-what-when and to verify that the employee qualifications at that time were appropriate. This means that the aspect of labor in the context of tracking and tracing has a strong relation to the plant activity (see further in ‘Production Methods’)

© 2000-2001 World Batch Forum. All rights reserved.
1.2.4 Facilities

Tracking and tracing information on facilities (like room conditions) is similar in nature as equipment. The information is mostly related to time.

1.2.5 Production methods (recipes)

As for the equipment model, the S88 concepts form a good backbone for the activity model. The master recipe structure in particular consists of:

- The header (recipe administration)
- The equipment requirements
- The formula (including ingredient inputs, product outputs and setpoints)
- The procedure (indicating the sequential flow of procedural elements)

It is our experience that the recipe model should be extended if we want to build full tracking and tracing. The S88 recipe defines ‘the necessary set of information that uniquely defines the production requirements for a specific product’. This indicates that a recipe is a plant operation that has the objective to transform a set of materials into another set of materials. However, in a production facility we find a lot of activities where you also have equipment requirements, a procedure and a number of setpoints, but there is no product involved, at least not in the sense that it is transformed into something else. Typical examples are the receiving of raw materials, refilling a work tank from a bulk storage and cleaning-in-place (CIP).

In our definition we’ll call this a plant activity. A special kind (a subclass for OO-freaks) of plant activity is a recipe because it also has the additional capability to transform product. Both terms are similar with respect to information management.

The smallest procedural element in a recipe or plant activity is a phase. The behavior of a phase for a particular recipe or plant activity is specified by phase parameters. Phase parameters can define material input, material output or ordinary process setpoints.

Each time a phase has been executed in the procedural flow of a batch, we dispose of a set of information typically containing:

- Start and end time of the phase
- Unit (equipment) were it ran
- Operator information (who, signatures)
- Phase specific events (state changes, …)
- Phase specific alarms
- Operator comments
- For each phase parameter:
  - Target value, limits, units of measurements
  - Actual value
  - If phase parameter is a material quantity, register consumed TraM IDs
  - Operator information (e.g. who entered, who signed)
By systematically storing this information for all phases executed in the recipe or plant activity, we build a full batch or plant activity record. You will notice in the data structure that we already established a link between an activity and the equipment. The start and the end timestamp will give us the window on the equipment information defined before.

When we think of a phase in S88 terms, we tend to associate this with an automated activity in a process control system. We must see this broader. A phase can be an interaction with the operator (operator input). This is especially useful when we want to include QC-sampling in the batch procedure sequence. By doing this you link QC information in an unambiguous way to process information.

There is also a link between the activity and the materials. As we already indicated, some phase parameters will specify a transfer of material. Taking the example of a recipe execution, we will have a set of parameters that define input of ingredients. The target value is a quantity associated with a material ID. The execution of the phase will lead to a physical material transfer between a source unit and a destination unit. This means that –when we register the information in the batch record- we can at the same time initiate a ‘transform’ inventory transaction as defined above (topic ‘materials’). This assumes that we have a possibility to know the TraM IDs that were used for the transfer. This can happen through operator input (e.g. weighing and dispensing in pharmaceutical industries, barcode scanning) but we can also implement this in automated transfers. If we move e.g. a quantity of sugar from a bulk silo to a mixer, we know that the bulk silo will behave like a FIFO (First In First Out) stack. Assuming we register incoming sugar deliveries appropriately, we can calculate individual quantities of the sugar traceable material IDs. For dosing from liquid tanks this translates in a MIX-picking algorithm (proportional picking of the TraM IDs in the tank).

You will notice that by executing S88 recipe procedures, a batch system is capable of transparently building the inventory transaction log that we discussed earlier.

### 1.3 Summarizing the information model

The schematic overview below summarizes the different types of information we discussed in the previous section.
In a detailed entity relationship diagram this information model explodes in a spider web of data structures. We will use this abstract model to illustrate what the activity of tracking and tracing embraces.

1.4 **To track and to trace as a verb**

The aim of tracking and tracing is to get to the right information records inside one of the 4 boxes in the figure above. The question of course is how to get there.

1.4.1 **Tools**

We need 5 tools for this job:

1. On **Plant Activity** we need a tool that gives us the possibility to browse inside the plant activity or batch record (including non-compliance reporting).

2. On **Inventory transactions** we need product genealogy reporting.

3. On **Equipment** we need charting and reporting tools giving us information on a particular time window.

4. **Facilities** is similar to Equipment.

5. And last but definitely not least we need a ‘Tracking and Tracing’ browser to navigate between the 4 entries.
It is especially the last one that merits some attention here.

### 1.4.2 Tracking and Tracing Browser

The lines between the boxes in the summarized information model indicate how we ‘jump’ from one information object to another. We will represent this in a matrix and explain the ‘jumps’.

![Matrix](image)

1. A time window on equipment leads to the same time window on facility where equipment is located.
2. Which TraM IDs used equipment during time period?
3. Which plant activity used the equipment during a time period?
4. A time window on facility leads to the same time window on all equipment located in facility.
5. Which TraM IDs used facility during time period?
6. Which plant activity took place during a time period in facility?
7. On which equipment has TraM ID been?
8. In which facilities has TraM ID been?
9. Which plant activities or batches have used TraM ID?
10. Which equipment has plant activity/batch used?
11. Which facilities has plant activity/batch used?
12. Which TraM IDs has plant activity moved or transformed?
1.4.3 A sample scenario

Assume that a QC sample on a pallet at the end of a production line indicated off-spec product. The QC analyst assumes a wrong dosing of a particular ingredient or possibly the raw ingredient that is off spec. Let’s have a look at his tracking and tracing activities using the 5 tools.

1. He gets a product genealogy report starting from the pallet lot number (TraM ID), upstream to the raw ingredients. Select a specific list of raw ingredients TraM IDs as suspects. (tool 2)

2. He checks the QC sample results on the raw ingredients obtained during the receiving plant activity. Therefore he looks at the plant activity record (tool 1). After checking all ingredients he does not detect off-spec results. He decides to request the QC lab for a re-analysis on one of the critical ingredients. The results are OK.

3. He gets an overview of plant activity that used a particular TraM ID (tool 5). He detects that Batch 123 has processed the material. He asks for a batch report (tool 1). Looking at this, he detects that the 3rd dosing step was aborted due to equipment failure. The dosing phase parameter actual value is out of spec. Bingo!

4. From the batch record, he obtains the TraM ID of the output product that was produced by batch 123. He asks for the downstream product genealogy (tool 2) to verify which other pallets (TraM IDs) were composed of this batch. These pallets are rejected. He also puts the pallets that came before and after the rejected pallets on hold until additional QC sampling proofs that it is OK to release them.

5. He further investigates and reports on the problem to avoid future occurrences.
1.5 Experiences

The tracking and tracing methodology as described in this paper has already been applied in different cases like Kraft Jacobs Suchard, BF Goodrich and others.

An important success factor is the availability of information that is reliable and transparent. In some cases this means compromising on things like accuracy, level of detail, number of operator inputs or the way exceptions are handled.

In pharmaceutical industries tracking and tracing is obviously a must. The presented methodology fits extremely well since batch recording and material identification is already seen as an intrinsic part of the plant activity.

In all cases the use of the S88 concepts was crucial for the implementation. It is only by using a rock-solid foundation of terms and methods, commonly applied over the different process stages in the plant, that we can keep the information management sufficiently simple and maintainable.