Workflow Support for Product Recall Coordination

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Abstract. When an organisation becomes aware that one of its products may pose a safety risk to customers, it must take appropriate action as soon as possible or it can be held liable. The ability to automatically trace potentially dangerous goods through the supply chain's workflow would thus help organisations fulfil their legal obligations in a timely and effective manner. Furthermore, product recall legislation requires manufacturers to separately notify various government agencies, the health department and the public about recall incidents. This duplication of effort and paperwork can introduce errors and data inconsistencies. In this paper, we examine traceability and notification requirements in the product recall domain in detail. We then show how legislated product recall requirements can be modelled as workflows and define the data and functional requirements needed for a workflow management system to support efficient product recall processes.

Keywords: Product Recall, Traceability, Workflow Management.

1 Introduction

Every organisation involved in manufacturing and the supply of food or consumer goods must be prepared for product recalls. In 2008 alone, there were over 1500 non-food consumer product recall notification announcements and over 3000 food and feed recall announcements in the EU [5, 6], around 1160 recall incidents in China, and 439 incidents in the US [17]. There have been a number of highly-publicised product recalls in recent years, such as Mattel recalling over 1.5 million toys in 2007 due to toxic lead paint [13], and the recall of many dairy products, including baby formula, due to melamine tainted milk in 2008 [23]. The impact of contaminated food and dangerous products can be devastating, resulting in numerous deaths. Manufacturers of such goods may be faced with lawsuits, and can suffer from serious loss of reputation. Hence, organisations must ensure that product safety is emphasised at all phases of the production process and they must have a detailed recall plan for "inevitable product recalls" [4].

Many countries have regulatory bodies which deal with product safety matters and provide guidelines on how to conduct product recalls. For instance, the US Food and Drugs Administration (FDA) sets out recall requirements in its Regulatory Procedures Manual [24]. Health Canada and the Canadian Food Inspection Agency coordinate product and food safety recalls [10]. In China, the General Administration of Quality Supervision, Inspection, and Quarantine oversees the safety of all locally-made products [15]. In Australia, product recalls are governed by the Australian Competition and Consumer Commission [3].

Manufacturers must therefore ensure that their products comply with national product safety measures and recall process standards. Typically, such guidelines are presented merely as checklists of actions to be performed. Here we develop a formal workflow model for coordinating a generic product recall process and for supporting efficient communication with all stakeholders. Such a process model can be used for carrying out trial recalls and as a first step toward fully automating the recall process. This will enable organisations to perform recalls efficiently and to effectively monitor their compliance with relevant legislation.

Two kinds of traceability are important for product recalls. Forward traceability is concerned with tracing end products that may contain ingredients from a particular supplier through the production process and the delivery network. For example, in Jan 09, the Kellogg company issued an industry-wide product recall on many of its products after one of their suppliers indicated that the peanut paste they supplied was potentially contaminated with salmonella [12]. Backward traceability is concerned with the ability to trace the supplier and the production process used for a particular product given its characteristics. For example, in Jul 09, a number of passengers on Virgin Blue flights became ill after eating chicken wraps contaminated with listeria bacteria [16]. The source of the contamination was eventually traced back to a processing plant in Wollongong.

Regardless of whether an organisation needs to conduct forward or backward tracing, it is important that appropriate data sets (e.g., supplier and order details, production logs and delivery records) and the relationships between these data sets are kept up to date for fast retrieval. Currently such data sets are often stored in different manual and automated filing systems with no easy way of correlating information between them. In particular, data requirements for traceability are rarely carefully thought out and planned in advance. The data gathering stage can be an ad-hoc activity in which an organisation has to gather relevant details as quickly as possible under enormous pressure. A crucial part of planning a traceability system involves "carefully researching and agreeing on what data is needed, how it will be entered, and how to provide the output" [20]. In this paper, we identify generic data requirements for traceability and explicitly capture the interrelationship between these data sets.

Many parties need to be notified during the recall process including suppliers, consumers, regulatory authorities, delivery companies, retailers, and health officials. Each of them has their own information requirements about a recall incident. Currently, it is time consuming for an organisation to prepare separate recall notification documents tailored toward each party. It is also easy to introduce data entry errors during the process. Therefore, we aim to determine the common data requirements for notification and to identify opportunities to automate the notification process as much as possible.

2 Product Recall Scenarios

In this section, we describe four distinct recall processes for different products: bread, frozen food, automobiles, and artificial heart pumps. Each recall scenario is based on an actual incident from the past few years¹. A common characteristic among these diverse products is that they are all produced via a component manufacturing process. However, their lifecycles differ in the number of suppliers involved, the nature of the manufacturing process, the shelf-life of the products, and the legal obligations for their traceability.

A generic manufacturing process consists of three main processes: (1) a materials intake process concerned with purchasing and warehousing supplies (e.g., raw ingredients, component parts), (2) a production process concerned with manufacturing finished products from these supplies using workers and machinery, and (3) a delivery process concerned with packaging the finished products and storing them in warehouses and/or shipping them to retailers using a number of distributors. To keep track of products for recall purposes, organisations use various product identification techniques including RFID tags, bar codes, batch numbers, lot numbers, serial numbers, etc. Furthermore, it is necessary to keep track of the equipment and workers involved during production and delivery.

2.1 Product Recall Scenario — Bakery

The basic ingredients for bread making include grain, water, and yeast. Sacks of flour and other ingredients are stored in warehouses. The baking process starts with mixing and kneading the dough in an industrial mixer. The dough is then fermented and then loaded into a divider that cuts it into pre-determined weights. A molding machine shapes the dough into balls and drops them onto a conveyor belt enclosed in a "prover". When the dough balls emerge, they are conveyed to a second molding machine which shapes them into loaves and drops them into pans. The pans travel to another prover before entering a tunnel oven. When the bread is baked, it is then sliced and passed to a wrapping machine. The bread loaves are then packed onto pallets and delivered to stores.

From a recall perspective, the interesting characteristics are as follows. The fact that a loaf of bread per se is not uniquely identifiable poses problems when a recall becomes necessary, so the best-before and manufacturing dates are used as surrogate ways to identify them. There is also no way to separately identify the ingredients once they are combined in the finished product. As a low-cost, high-volume commodity, bread has an extensive distribution network involving many small businesses who directly use or on-sell loaves. To enable forward tracing, it is necessary to keep accurate records of the raw materials used during production. For instance, workers must make records of which sacks of flour, identified by lot number, were used on a certain day. In addition, we need to keep track of the workers and equipment involved in the baking process.

¹ However, the generic process descriptions are based on those in www.madehow.com.

Consider a scenario where customers report finding foreign objects in bread loaves. The investigation finds that a disgruntled employee, say 'John', has been deliberately tampering with the products. In this case, the organisation needs to find answers to the following questions (from various data sources) quickly.

- What was John's work schedule in the last few weeks (employee records)?
- Which batches were worked on by John on those days (production data)?
- What are the identifying features of suspect products (product data)?
- Where are the potentially contaminated batches now (distribution data)?

2.2 Product Recall Scenario — Frozen Food

The process starts by preparing the raw food ingredients (e.g., pasta, meat, vegetables) first. All these ingredients are then cooked and placed into trays before the trays are frozen quickly (the temperature can get as low as -59° C). The frozen food is then put into cardboard cases and the batch numbers and best-before dates are printed on the packaging. These cases are then loaded into pallets and placed in a refrigerated storage facility. They are then transported in refrigerated trucks to retailers. The food will remain in near perfect condition if it is kept at -18° C during shipping and storage.

From a recall perspective, food safety is directly linked to the proper handling and preparation of food during production as well as transportation. In this case, it is important to keep track of temperatures inside the storage facilities and in refrigerated trucks. As the shelf-life of frozen food can be up to a year, production schedule data needs to be kept for at least that long.

Consider a scenario where customers report getting sick after consuming the product. The manufacturer needs to find out whether there are some production lines for which temperatures inside the freezer and the refrigerated truck were not low enough (e.g., higher than -30° C in the freezers or higher than -10° C in the trucks). Answers to the following questions are required quickly.

- Were there batches in freezers with a high temp (production data)?
- Were there batches in trucks with a high temp (distribution data)?
- What are the identifying features of the suspect products (product data)?
- Where are these batches/lot numbers now (distribution data)?

2.3 Product Recall Scenario — Motor Vehicles

An automobile assembly plant uses components from more than 4000 outside suppliers, including company-owned parts suppliers. Car frames are placed on an assembly line and moved to assembly areas where various components are installed. For heavy component parts, articulated robots perform the lift-and-carry operations while assemblers bolt pieces in place. The body is built on a separate assembly line. The vehicle is then painted and cured in baking ovens. After the internal components are installed, the vehicle is inspected. When the vehicle passes final audit, it is driven to a staging lot to await shipment. A Vehicle

Identification Number (VIN) is assigned at the start of the production line and a monitoring unit keeps track of a vehicle's progress along the assembly line.

From a recall perspective, even though the number of suppliers is huge, they are well-known and the parts well-labelled. As a vehicle goes through so many different steps during assembly, accurate recording of the manufacturing sequence is essential. There is collaborative work between workers and robots that should be recorded as well. The VIN number provides a unique identifier for the finished product. Sometimes, the buyer's information in addition to the dealer's information can be found for a vehicle at the time of recall.

Consider a scenario where mechanical problems with one of the robot arms, R1, are detected during its six-monthly inspection, as a result, it is possible that the welds produced by this robot could fail. The issues in this case are as follows.

- Which VINs were worked on by R1 in the past six months (production data)?
- Where are these cars now (distribution data)?
- Are there any customer records for these cars (customer data)?

2.4 Product Recall Scenario — Heart Pumps

An artificial heart is made out of metal, plastic, ceramic, and animal parts. Most components are custom made by third party manufacturers. Each heart consists up to 50 components put together using special adhesives. Several assembly operations happen in parallel, including the assembly of the motor housing and components, the assembly of the percutaneous tube and the attachment of the pusher plates to the polyurethane diaphragm. The final assembly of the complete system occurs after careful inspection. Each device is sterilized and sealed in a plastic tray, packaged in a custom suitcase, and sent to distributors.

From a recall perspective, this process involves a small number of suppliers with well-labelled components. The assembly process is straightforward with strict quality control measures. Every component, including adhesives, used in the process is controlled by lot and serial numbers so that it can be traced.

Consider a scenario where a component from a particular supplier, S1, is found to be defective during testing and the serial numbers of defective components have been provided by the supplier. The company must now determine which heart pumps to recall, so it needs to answer the following questions.

- Which heart pumps, identified by serial numbers, used defective components from supplier S1 (production data)?
- Where are those heart pumps now (distribution data)?

3 Product Recall Coordination

The case studies in the previous section show that there are a wide variety of recall scenarios, involving different data recording, traceability and notification requirements. To produce a generic workflow model for product recalls we reviewed recall standards from Australia, the United States, the United Kingdom

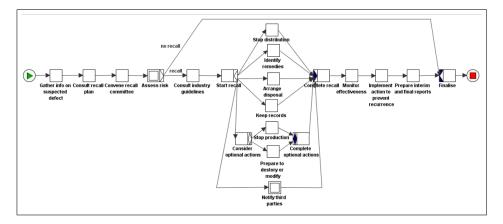


Fig. 1. A generic product recall process

and the European Union. We also consulted a number of food and non-food product recall standards and associated guidelines. Finally, we interviewed relevant personnel from Queensland Health, the Australian Food and Grocery Council, and an Australian food manufacturing company with product recall experience.

Clearly, effective and efficient tracing of suspect products is essential for a successful recall. It requires that information from different sources, including Enterprise Resource Planning systems, Human Resources systems, logistics systems and manual on-site records, is gathered and correlated to get an accurate picture of the recall's scope. We also noted high overheads associated with satisfying regulatory bodies' documentation and notification requirements.

3.1 A Generic Product Recall Process

In this section, we present a generic product recall process using the YAWL notation (Fig. 1) [1]. The model is based on product and food recall guidelines in Australia [3,7]. It was also validated against guidelines from the US and the EU. The process describes the main activities undertaken by a recall sponsor, typically the manufacturer of a suspect product. Recall incidents may be triggered by consumer complaints, supplier notifications, failed quality assurance tests, etc. It is also possible that there are extortion threats made against a company, such as those faced by Arnotts in 1997. In each case, the manufacturer is responsible for investigating the problem thoroughly and carrying out a comprehensive risk analysis (c.f., the assess risk subprocess in Fig. 1).

A decision can then be made as to whether the product should be recalled or not. If a decision is made to recall a product, the manufacturer must consult and follow relevant industry guidelines. The manufacturer also takes appropriate actions to stop the distribution of its products, identify remedies, arrange storage and disposal of the contaminated products and keep records to evaluate the recall's effectiveness. Depending on the type of product and the defect responsible

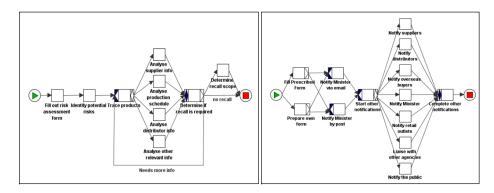


Fig. 2. (a) The risk assessment subprocess (b) The third-party notification subprocess

for the recall, the actions taken by the manufacturer could also include halting production of the product and destroying potentially contaminated products.

In addition, the manufacturer must notify third parties about the recall. (In Fig. 1 this notification activity is modeled by the *notify third parties* subprocess.) It is also important that the effectiveness of the recall process is closely monitored. The manufacturer can then implement necessary changes to prevent a recurrence of such problems. The regulatory authorities can also request evidence of the recall's effectiveness from the manufacturer, so the manufacturer is obliged to keep appropriate records about the recall incident. Required reports are then prepared and sent to interested parties.

The assess risk subprocess (Fig. 2(a)) describes the main steps involved in carrying out a comprehensive risk assessment. The outcomes of this process are to decide whether to recall and to determine the appropriate recall scope. It is very important to get the scope right for a recall as too narrow a scope could mean that unsafe products are still left in circulation and too wide a scope could add millions of dollars in lost revenue. To make the recall scope decision, it is essential that adequate information is provided to the decision maker. In our model, these decisions are modelled as two manual tasks (determine if recall is required and determine recall scope). The information requirements for these decisions are provided by the four preceding data analysis tasks. The process model depicts the main data sources (supplier information, production schedule, and distributor information and other relevant information, e.g., quality assurance test results).

The notify third parties subprocess (Fig. 2(b)) shows the various stakeholder notifications that must be produced in a timely manner during recall. Some regulatory bodies prescribe a specific form that must be used for recall notifications, while others leave this to the manufacturer. Different means of contacting the various parties are also allowed depending on the urgency of the situation. From our investigations, we noted that the majority of the information required in these forms is standard (e.g., the description of the product being recalled, the reason for the recall, the instructions on how to remedy the problem) while some other extra information could be required for particular cases (e.g., con-

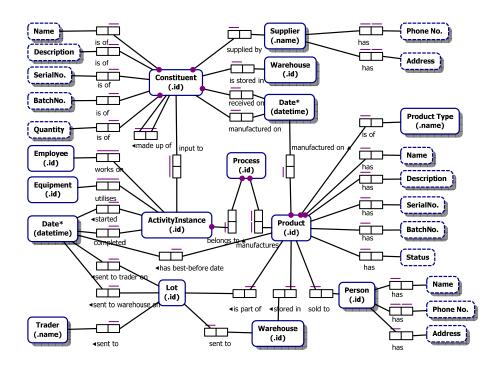


Fig. 3. Data model for product traceability

tact details for distributors, other identification features specific to the supply chain, bank account details for recovering recall expenses, etc.). Despite the large amount of standard data required for notifications, in practice organisations still fill in these forms manually, which is both inefficient and error-prone.

3.2 Data Requirements for Product Traceability

From this understanding of the recall process and associated standards we identified the data requirements for traceability needed to trace a product from its origin, through the production process, and finally to the consumer. To achieve end-to-end traceability, it is essential that adequate data sets are kept for each product and that, most importantly, the relationships between these data sets are maintained. The Object-Role Model [9] in Fig. 3 depicts the main data attributes that must be captured to enable end-to-end product traceability. The main categories of data are as follows: (1) Materials Intake data associated with the product's constituents (e.g., details of raw materials obtained from suppliers and their storage locations), (2) Production data associated with the production process. We explicitly model the fact that a particular constituent is an input to a particular activity, as well as the details of workers and equipment em-

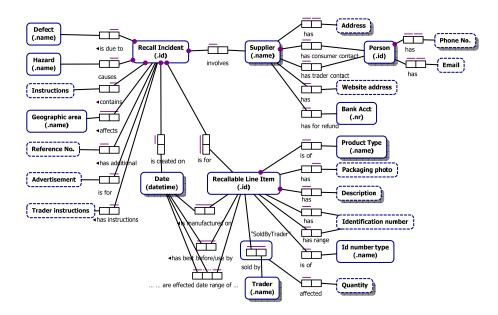


Fig. 4. Data model for recall notification

ployed during production, (3) Final Product data associated with the product itself (e.g., serial numbers, batch numbers, and best-before dates), and (4) Delivery data associated with the storage and delivery of the product, including lot numbers, warehouse locations, traders and customers.

3.3 Data Requirements for Recall Notification

The recall standards require stakeholders to be notified about recall incidents in specific ways, e.g., direct communication, published recall notices, etc. We consolidated these needs to identify general data requirements for recall notification. These are primarily concerned with ways of describing suspect products (e.g., unambiguous product descriptions, packaging information and photos). The Object-Role Model in Fig. 4 depicts the main data attributes that are required in notification forms. The main categories of data are as follows: (1) Recall incident data about the reason for the recall and the instructions on what to do with suspect products, (2) Supplier data associated with the supplier of the recalled product including their contact details, (3) Identification data associated with the product type generally and recalled items specifically, including photos of the packaging where applicable, and (4) Trader data associated with traders who sell the product.

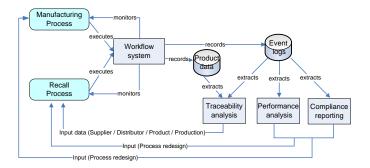


Fig. 5. A workflow-based coordination framework for product recalls

3.4 Framework Overview

We propose the use of workflow technologies to conduct product recalls in a more efficient manner (see Fig. 5). An organisation's manufacturing process and product recall process can be enacted and monitored within a workflow environment. Workflow systems typically capture event logs (e.g., activities, timestamps and resources) as well as other data attributes used during the enactment. For recall purposes, workflow systems can record data attributes required for traceability and recall notification as the workflow is being enacted. This approach enables ready access to relevant data when a recall incident occurs. Using the data from event logs, we can perform a detailed traceability analysis to decide on the recall scope, undertake performance analysis of both the manufacturing process and the recall process, and finally ensure that the undertaking of a particular recall incident is in compliance with relevant legislations.

4 Prototype Implementation

We now demonstrate the proposed approach using the YAWL open-source work-flow framework [1] and the process mining framework ProM [2] (See Fig. 6). The bakery process was captured as an executable workflow to illustrate how the product recall data requirements can be captured. The generic recall process is also enacted to illustrate how a product recall can make use of the log data.

4.1 Capturing Recall Data Using a Workflow System

Fig. 7 describes a simplified commercial bread making process based on the process description given in Subsection 2.1. The process constructs have been intentionally kept simple as the focus here is on the data requirements. Complex XML data types were used to capture the data requirements of the process based on the traceability ORM model given in Section 3. The process was then run a number of times within the YAWL engine with mock data. The engine logged the production schedule (i.e., activities, event timestamps and resources used as

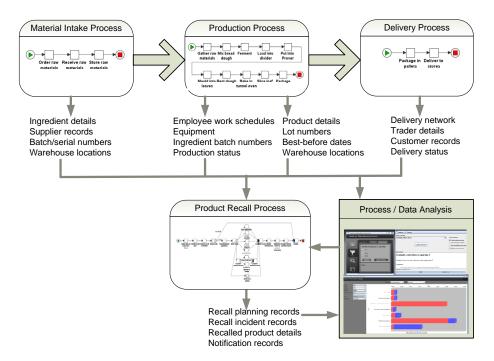


Fig. 6. A product recall demonstration using the YAWL and ProM frameworks

default) and other data attributes that are associated with the process. These logs were then stored in a database and retrieved later for analysis.

4.2 Handling a Potential Product Recall Incident

When a potential product recall incident occurs, an organisation must initiate an investigation into this incident and start off the recall process. By using an automated solution for product recall, an organisation can respond to these incidents in an effective and efficient manner. A generic recall process is depicted as a YAWL process in Fig. 1. The traceability requirements and the notification requirements for the process are modelled as XML data attributes in the process.

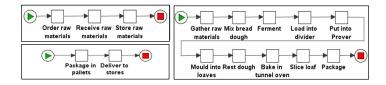


Fig. 7. Bakery - Materials Intake subprocess and Delivery subprocess (left) and Production subprocess (right)

Using the bakery scenario with disgruntled employee 'John' described in Subsection 2.1, we can answer the questions posed previously using the information from logs. We used ProM to carry out the traceability analysis, however, it is also possible to retrieve these data sets and correlate them directly using the custom service feature in YAWL.

During the notification process, the data attributes stored during the assess risk subprocess are used to automatically pre-fill the notification forms for various stakeholders. As well as routine data about the manufacturer (company name, contact details, etc) and the product generally (description, photos, etc), specific data about the suspect items can be extracted from the logs (manufacturing dates, best-before dates, batch numbers, etc).

4.3 Recall Data Analysis Using a Process Mining Tool

Once basic production and delivery data is captured by the workflow system as explained above, we can then use a process mining tool such as ProM [2] to extract and present the information typically needed during a product recall.

- Traceability Analysis: For backward and forward traceability purposes, we can use the following features of ProM to analyse data for recall scenarios provided in Section 2. For instance, for the product tampering example by an employee in a bakery, the logs are filtered by time (e.g., two weeks) and then by the employee who worked on the product using the originator log filter (See Fig. 8 top-left). Similarly, for the contaminated frozen food scenario, we can filter the production and the distribution logs based on a certain temperature value using the attributes value filter. We can also use the basic log Statistics feature to identify the temperature range logged during the frozen food production process. For the robot arm welding problem in a motor vehicle manufacturing plant, the logs can be filtered based on the equipment id using the attributes value filter.
- Performance Analysis: There are a number of performance analysis features in ProM that can be used to monitor the effectiveness of a recall. The log summary feature provides an overview of all the recall incidents conducted by an organisation. We also used log summary and performance analysis features to gain insights into the timing and the actions taken during a recall (see Fig. 8 bottom).
- Compliance Reporting: Using the process discovery feature available in ProM and the detailed log data from a recall process, it is possible to ensure that a recall process conducted by a particular organisation is compliant with the legislative requirements imposed by a particular country. We can also evaluate whether the required notifications are sent to the authorities within the requested time frame using the LTL checker (see Fig. 8 top-right).



Fig. 8. Examples of product recall data mining using ProM

5 Related Work

Much research has been done on product traceability. Regattieri et al. presented a general framework for a food traceability system and illustrated how it can be used together with alphanumerical codes and radio frequency identification (RFID) tags [18]. However, the framework described is very abstract and the company has full control over the process. Ruiz-Garcia et al. also proposed a traceability system for agricultural production and fruit transport using batch codes and a web services framework [19]. Setboonsarng et al. discussed food safety requirements in Japan and the use of ICT technologies via two case studies [20]. Sugahara proposed use of RFID tags and mobile technology for traceability in Japan's agricultural industry [22]. Our framework can be used with any type of applicable product identification techniques.

Some have proposed the use of reverse distribution networks to recall defective products within a logistics framework [14,11]. Their research proposes the use of a central database for information storage. The workflow process perspective of product recalls has been largely unexplored. Also a central database might not be feasible when dealing with a large number of players within a supply chain. We instead exploit the coordination capabilities of workflow systems to link data stored in different systems.

The introduction of recall notification systems in the European Union, the United States, Canada and China highlighted the need for automating recall

notifications. For countries within the European Union, there is the RAPEX system for non-food consumer products and the RASFF system for food and feed [5,6]. After the lead paint scandal in 2007, the Chinese government put in recall systems for unsafe food products and toys [15]. The workflow requirements presented in this paper could be used to coordinate these stand-alone recall notification systems with the remainder of the overall recall process.

There are also commercial tools for managing recalls in the manufacturing industry. They are primarily intended for products that are still within the confines of the factory or warehouse [8]. They allow an item's first port of call to be identified, but it is expected that each of these distribution points will then be contacted individually in order to determine what has happened to the item in question [21]. Once again, our workflow model offers a way of linking these systems into the end-to-end recall process.

6 Conclusion

Conducting a product recall is a complex process involving many stakeholders. It is both time- and safety-critical, and is subject to government regulation. A successful product recall requires coordination of many tools and processes for tracing products, generating various notifications and demonstrating compliance with regulations. Here we presented a workflow model of the overall process and detailed data requirements needed to support it. We have also shown how a workflow management system could be used to make product recalls more efficient and effective, by coordinating existing manufacturing tools and processes.

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