SANYO DENKI

Quality Control Course for Career Development Education

The "Basic Knowledge of Techniques to Prevent Problems in Advance" Course

SANYO DENKI CO., LTD.
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Contents of This Course

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<Purpose>

- The purpose of this training is to help you understand that activities that prevent defects in advance are important for the company, and to give you an overview of what kinds of preventive methods are available.

<Contents>

1. Preventing Defects in Advance refers to
2. FMEA
3. FTA
4. DRBFM
5. Unintended Change Management
6. Utilization of Past Information about Problems

1. Preventing Defects in Advance refers to

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① Preventing Defects in Advance refers to

Preventing defects in advance refers to taking preventive measures before defects such as accidents and quality problems occur in products and at manufacturing sites, in other words, it refers to "activities to prevent defects in advance".

② Difficulty of preventing defects in advance

Measures against defects and cause investigations target problems that are already visible, however, preventing defects in advance is a rather difficult task, because you need to assume the existence of problems that are not visible now, and take preventive measures.
It requires skills and techniques that are different from problem resolution.

You need to work by using your imagination to identify problems, and by using the method of preventative measures to stimulate your imagination.

How can I prevent defects in advance?

1. Preventing Defects in Advance refers to

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③ What are the factors that make preventing defects in advance unsuccessful?

- Past information about problems is not utilized to prevent defects in advance
  When a problem occurs, we investigate to resolve the problem and take appropriate measures.
  If the investigation does not identify the root cause of the problem, we will not be able to obtain useful information.
  While trying to solve a problem, the desire to resolve the problem quickly may lead to a quick fix.
  Preventive measures found under these circumstances may not be useful for preventing problems in advance, or for preventing recurrences.

- Defect information is not utilized when making assumptions about defects
  Defect information can help identify failure modes and identify risks.
  Problem information is not organized, centrally managed, and cannot be searched, and therefore, past experience may not be utilized to prevent defects in advance.

- The positive outcomes of preventing defects in advance are difficult to see
  Implementing preventive measures is a difficult task involving taking measures in advance for future risks that are not yet visible.
  The "achievement of preventing defects in advance" is a very significant achievement for an organization, however, the absence of problems is an achievement that is difficult to see or identify.
  Preventing defects in advance can be a task that cannot be highly evaluated, and thus it may be prone to becoming a mere formality.

2. Method of Preventing Defects in Advance (FMEA)

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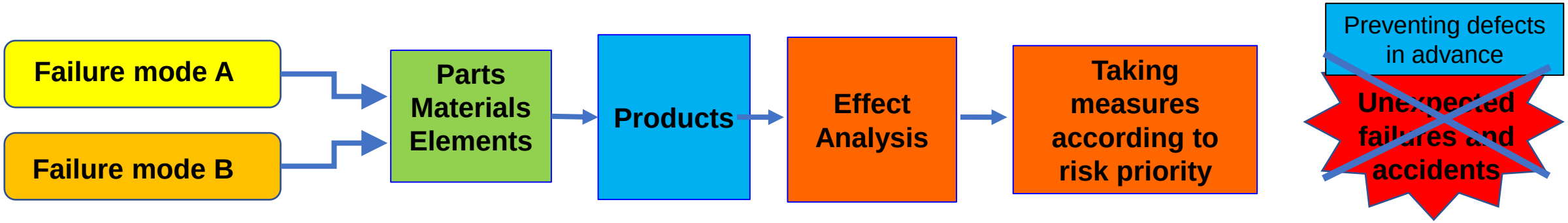
① FMEA refers to

FMEA
(Failure Mode and Effects Analysis)

Refers to a design reliability evaluation method used to analyze how the failure affects the system if the parts, materials, elements, etc. that make up the system fail, and to eliminate the most critical failure modes in advance. It is a bottom-up analysis tool that identifies unexpected failures and accidents of products without omission, starting from the failure mode of parts, materials, elements, etc.



Bottom-up:
What failure modes are there for parts, materials, and elements? (Identification of Failure Mode: FM)
How does the failure mode affect products and systems? (Effects Analysis: EA)
Identify the causes of potential failures and accidents and take preventive measures.

2. Method of Preventing Defects in Advance (FMEA)

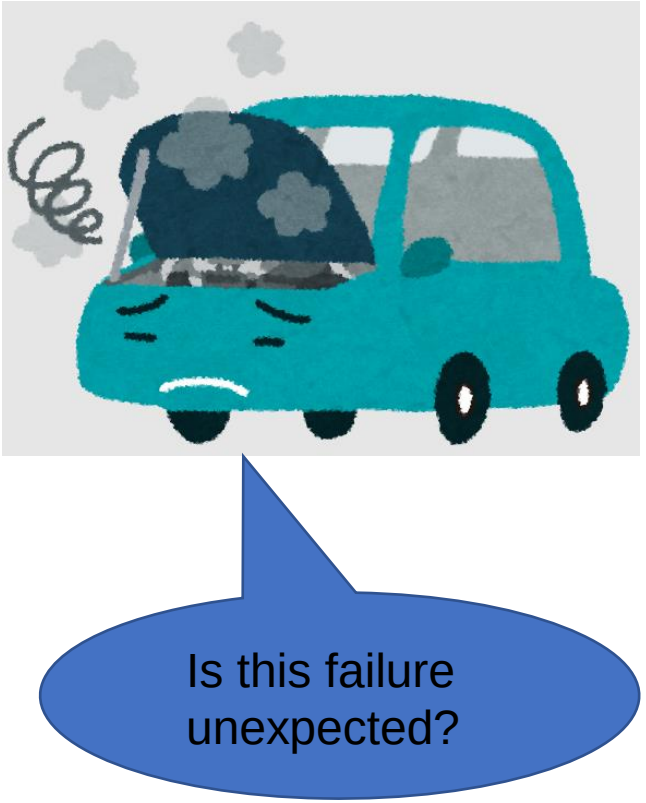
② Expected Effects of FMEA

When a new design is being created or when intended changes are being made to the design, the failure modes of parts, materials, elements, etc. and the causal relationships between their effects are made clear, and their respective weaknesses and concerns are identified.
For failure modes judged to be highly critical (high risk priority) in this analysis and evaluation, it is necessary to incorporate preventive measures at the time of design.

By clarifying the mechanism leading from a failure mode to failures based on the way the product is used in the market, environmental conditions, etc., it becomes possible to identify the failures that are expected to occur.

Since it is possible to identify failure mechanisms caused by problems in quality control and process management, it is possible to take appropriate measures in advance.

FMEA can be applied to various applications such as process FMEA, inspection FMEA, and unintended change FMEA.



2. Method of Preventing Defects in Advance (FMEA)

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③ FMEA Implementation Procedure

Block name/part name, process name
For design FMEA, enter the block name or part name.
For process FMEA, enter the process name.

Failure mode
List possible failure modes for blocks, parts, and processes, identify unexpected failures and accidents, and evaluate their effects.
In order to identify potential defects that cannot be identified by evaluation tests or inspections, it is also necessary to possess the knowledge to consider the effects of usage.

Effect of failure
Consider not only the effects on individual products, but also the effects on the entire system.

Causes and Mechanisms of Failure
Listing up failure modes alone does not lead to creation of appropriate measures.
It is important to analyze the mechanism that leads to failure, and connect it to measures.

Probability/Severity/Detection
Described in the next section.

Rating (Risk priority number: RPN)
RPN = Probability × Severity × Detection
The higher the RPN, the higher the risk priority.
In addition, write down on the sheet how the RPN will decrease after taking measures.

[FMEA Worksheet Example]

Block name Part name Process name	Function	Failure mode	Effect of failure	Causes of failure Mechanism	Pro-bability	Severity	Detec-tion	Rating	Measure
Relay	Control of XX	Does not turn off	If the customer's device could not control XX, it would become a major accident.	Short circuit due to adhesion of foreign matter	2	5	5	50	Use a cover to prevent foreign matter from entering
				Part failure	1	5	5	25	Provide redundancy in order to prevent a single failure from causing an accident
				XXX					
			XXX						
		XXX							

The contents described as examples are fictitious contents unrelated to our products.

2. Method of Preventing Defects in Advance (FMEA)

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③ FMEA Implementation Procedure (continued)

Evaluation of Probability
Evaluate the probability (likelihood of occurrence) of the failure mode.
Divide probability into multiple stages in advance, from those that are certain to happen, to those that are unlikely to happen at all.

Evaluation of Severity
Evaluate the severity of the effect of the failure mode.
Divide severity into multiple stages in advance, from those that will have a serious effect on safety, to those that will have no effect on safety or quality.

Evaluation of Detection
Evaluate the difficulty of detecting failure modes (the difficulty of detecting potential failure modes in advance before they are offered to customers).
Divide failure modes into multiple stages in advance, from those that cannot be detected in advance at all, to those that can be detected reliably in advance.

[Example of Probability Evaluation]

	Rating	
Probability	5	Persistent, occurs daily (always)
	4	Occurs about once a week (frequently)
	3	Occurs about once a month (quite frequently)
	2	Occurs about once a year (occasionally)
	1	Occurs about once every five years (rarely)

[Example of Severity Evaluation]

	Rating	
Severity	5	Critical failure that could lead to product liability issues
	4	Product stopped functioning (leading to replacement)
	3	Partial stoppage of a function (alarm)
	2	Minor failure in appearance, function, etc.
	1	Failure that occurs to the extent that the customer does not notice it

[Example of Detection Evaluation]

	Rating	
Detection	5	Detected in the market while used by users
	4	Detected by spiteful usage test/user commissioning
	3	Detectable before ET/QAT/shipment
	2	Detectable in prototype evaluation
	1	Detectable by basic characteristics evaluation

[Example of Detection Evaluation (Process FMEA)]

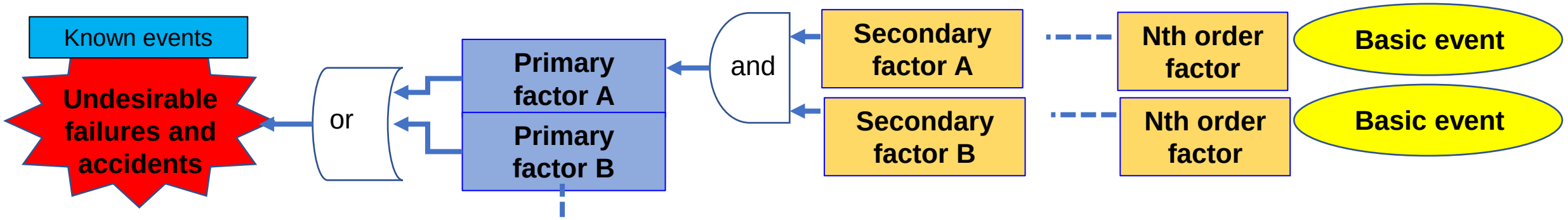
	Rating	
Detection	5	While used by users
	4	Difficult to detect by inspection
	3	Detectable by inspection
	2	Detectable on the next process stage
	1	Detectable in our own process

3. Method of Preventing Defects in Advance (FTA)

① FTA refers to

FTA
(Failure (Defect) Tree Analysis: Fault Tree Analysis)

This is an analysis method used to qualitatively and quantitatively grasp the relationship between the top event and its causes by sequentially investigating causes starting from an unfavorable event (top event) and moving to lower levels.
In order to identify the basic circumstances that cause top events, FTA starts with the top event and identifies the lower causal factors hierarchically in a top-down manner.



Top-down:
Undesirable failures and accidents are caused by primary factors.
(In the figure above, if either primary factor A or primary factor B occurs, an undesirable failure or accident will occur.)
Primary factors are caused by secondary factors.
(In the figure above, primary factor A occurs when both secondary factor A and secondary factor B occur.
Analyze the lower factors that cause the higher factors, and drill down to the basic event (cause).

3. Method of Preventing Defects in Advance (FTA)

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② Expected Effect of FTA

FTA can be used as an analysis method to identify "top events" that are serious problems for products, to clarify the causal relationship of the factors causing the events by digging deeper into the tree of causes, and to implement measures to prevent the occurrence of top events in advance.
In this kind of preventive usage, we start with the assumption that "what if a failure occurs", analyze what factors would lead to the assumed failure, and strengthen the weak points.

In FTA, the factors that cause the top events to occur are summarized in one chart, which has the advantage of showing the relevance of each factor at a glance.

FTA is also used to investigate the cause of an accident or failure that has occurred, and if the Fault Tree Diagram is made without omissions or oversights, the cause is in this Fault Tree Diagram. By eliminating factors with careful corroboration, you can arrive at the cause.

3. Method of Preventing Defects in Advance (FTA)

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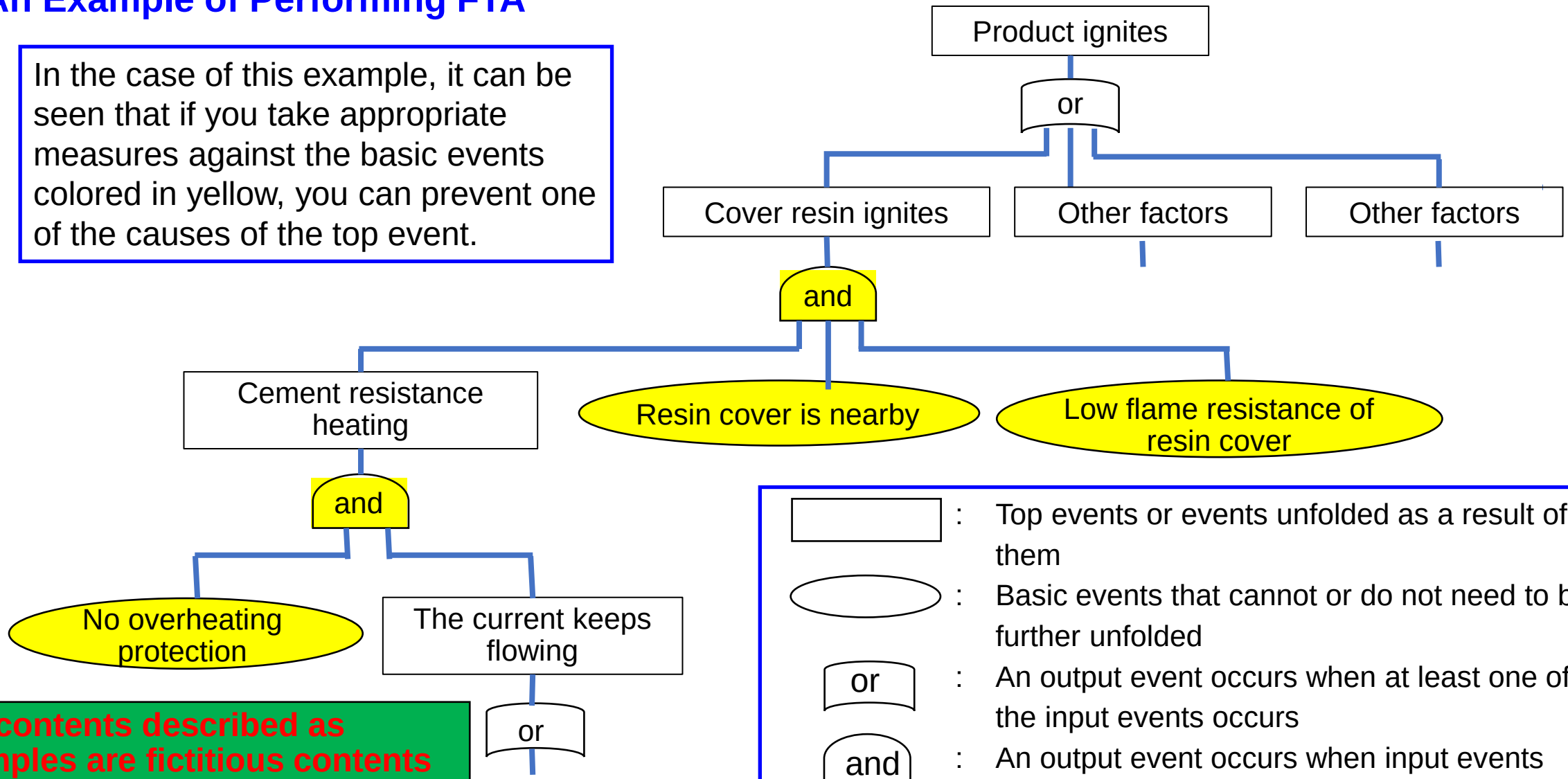
③ An Example of Performing FTA

In the case of this example, it can be seen that if you take appropriate measures against the basic events colored in yellow, you can prevent one of the causes of the top event.



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▭	:	Top events or events unfolded as a result of them
⬭	:	Basic events that cannot or do not need to be further unfolded
or	:	An output event occurs when at least one of the input events occurs
and	:	An output event occurs when input events occur simultaneously.

4. Method of Preventing Defects in Advance (DRBFM)

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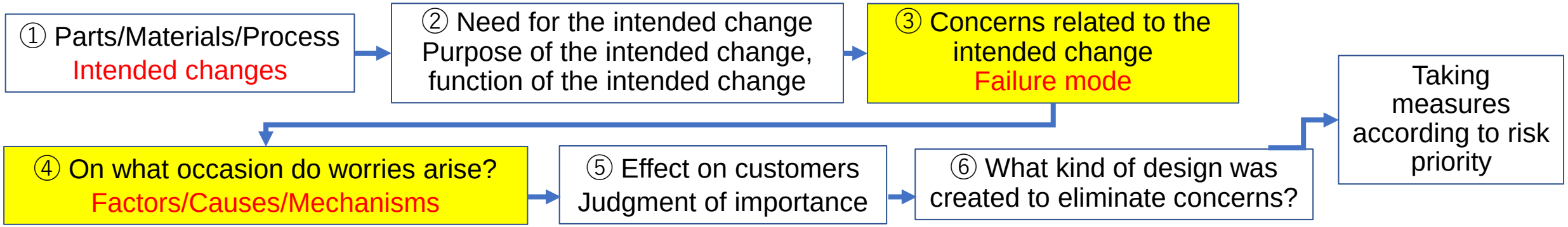
① DRBFM refers to

DRBFM
(Design Review Based on Failure Mode)

DRBFM is a method used to prevent risks due to intended changes from conventional designs and processes. Therefore, it is a method used to improve product reliability by identifying potential problems and risks through design reviews in the design stage.
DRBFM is similar to FMEA in that it focuses on failure modes, however, it differs in that it focuses on intended changes.



Flow of Design Review:
The designer prepares the DRMFM worksheet with items ① through ⑥ above written down on it.
Regarding ③ and ④, the relevant parties discuss whether there are any other omissions in the contents extracted in advance by the design side.
According to the result of DRBFM, list the items that need to be reflected in design, evaluation and process management and take appropriate measures.

4. Method of Preventing Defects in Advance (DRBFM)

② Expected Effect of DRBFM

DRBFM is used to focus on intended changes from existing proven products, to clarify failure modes and failure mechanisms caused by intended changes, and to produce designs to eliminate concerns regarding intended changes.
Competition in product development is intensifying, and it is becoming necessary to develop a wide range of products in a shorter period of time than before. Even in situations where it is necessary to shorten the development time, by focusing on the intended changes, it is possible to conduct a design review that uses time and resources effectively, and to improve product reliability during the design stage.

It is important that members from various departments, such as design, production technology, production, and quality, participate in the design review and share their wisdom to increase product reliability.
Design review does not mean that only designers take suggestions and make improvements. It is also necessary for the on-site departments to cooperate to build up reliability.

DRBFM is conducted by a team.
Let's share information and improve reliability.

4. Method of Preventing Defects in Advance (DRBFM)

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③ DRBFM Implementation Procedures

[Part names, process names, intended changes]
List all the intended changes that may affect the performance, characteristics, and functions of the product.
In addition to the intended changes, also list the unintended changes, such as ambient temperature and vibration.

[Function]
Describe the function that the target of the intended change should originally perform. The opposite of an expected function is a failure mode.

[Purpose of the intended change]
Describe the reason and purpose of the intended change.

[Concerns caused by the intended change]
Describe the failure modes (factors that inhibit function) corresponding to the function.
It is important to consider concerns from the viewpoint of users (the entire system).

[Under what conditions do concerns arise?]
Focusing on the intended changes, consider specifically when the concerns arise and the factors and causes behind them.

[Effects on customers]
From the customer's point of view, analyze the severity of effects on the product or the system in which the product is used.

[What kind of design was created to eliminate concerns?]
Enter the items for which the design has been reviewed in advance in relation to the cause of concerns (such as design verification record).

[DRBFM Worksheet Example]

Part name Process name Intended changes	Function	Purpose of the intended change	Concerns caused by the intended change		Under what conditions do concerns arise?			Effects on customers		What kind of design was created to eliminate concerns?
			Loss of functionality caused by the intended change	Are there any other concerns?	Pro-bability	Causes Factors	Are there any other factors to consider?		Criti-cality	
Change heating temperature from 200°C to 250°C in the drying process of the part XX	**Stabilize electrical characteristics**	**Cost reduction**	**Deformation of XX section**		**Medium**	**Excessive thermal stress**		**Poor electrical characteristics**	**Large**	**Define the upper limit of the XX section (stress relaxation)**
				Discoloration of XX section	**Low**		**The temperature is high**	**Poor appearance**	**Small**	**Check the storage temperature of XX**

The items in yellow are items that are reviewed, discussed, and filled in by related parties.

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① Unintended Change Management

Unintended Change Management

When there are any intended changes or unintended changes, the quality characteristics of the product are prone to change.
It is necessary to establish rules for responding to intended and unintended changes and to check by paying attention to whether there are any effects on quality characteristics.

[Example of management item standards]
(Not our standards)

3 Hs

4 Ms

	Unintended change (Henka)	First time (Hajimete)	Long time no see (Hisashiburi)
Man	Workers, supporters, change in number of people	Newcomers, reassignments, supporters	After long holidays, Return to work
Machine	Repair, inspection, maintenance, short time stoppage for repair, cutting tool replacement	Newly introduced (Equipment, molds, jigs, etc.)	Restart of idle facilities
Material	Material, standard, manufacturer Lot	New materials	Long-term storage materials First purchase in a year
Method	Processing conditions, work procedures, storage conditions, layout	First time manufacturing	First work in a year
Measurement	Measuring instruments, inspection standards Sampling conditions	First measurement/inspection	First measurement and inspection in a year
Environment	Transfer of plant and line	New workplace, new line	Restart of idle lines

5. Method of Preventing Defects in Advance (Unintended Change Management)

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[Example of how to proceed with management] (This example does not describe our management method)

①. Decide whether to start management by checking with the [Standards for Management Items].

↓

②. Coordinate with relevant departments if necessary

↓

③. Determine management items according to the details of the intended changes

↓

④. Implement the flow management after the intended change

↓

⑤. If there are no problems after a certain period of time and a certain number of units are produced, the flow management is terminated.

[Intended change management example]
"Intended Change Specialty Board" used by the Servo Systems Division

[Unintended changes]

In the field, not only intended changes but also unintended changes (abnormalities) occur.
If such unexpected abnormalities are overlooked or neglected, the result is often a change in the quality characteristics of the product.

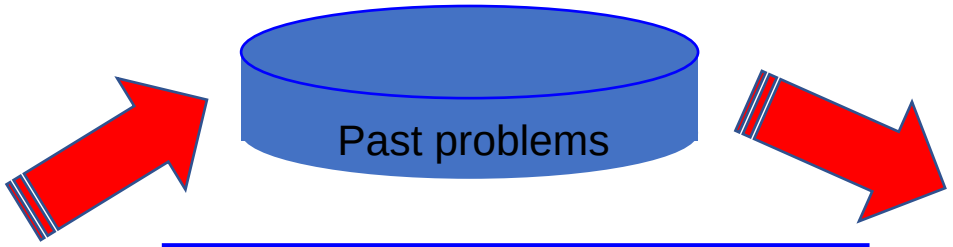
Establishing rules, such as contacting superiors and receiving instructions from managers, is also an important activity aimed at preventing defects in advance.

Utilization of Past Information about Problems

The purpose of utilizing past information about problems is to make use of experience to prevent similar problems from occurring by referring to problems that have occurred in the past.
It can also be used effectively for creating a recurrence prevention checklist and for FMEA, FTA, and DRBFM.
By learning lessons from past information about problems and utilizing them to create measures, significant advances can be made in terms of preventing defects in new products.
Past information about problems may be held by individuals or within a single department.
Centralizing information as organizational knowledge and managing it as a database that anyone can refer to is a good method of effective utilization.

Anyone can input data easily
It is possible to register promptly from the time a problem is discovered

- Able to manage problems without exception
- Able to accumulate past problems without omission
- Always able to input fresh information



It is necessary to increase the value of past information about problems.

Anyone can use it easily

- Searchable by keyword
- You can get the information you want
- The information about cause and preventive measures is reliable.

7. Summary

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This course covered the basics of prevention and prevention methods.
In the QC department, we have experienced many actual defects that occurred in the past that are related to “unexpected” and “unintended change”.

Methods for dealing with factors of "unexpected" and "unintended change" are also addressed in the methods of preventing defects.

If the following two points can be achieved, the number of defects will be greatly reduced.

- Take preventive measures in advance by assuming the causes of defects that have not yet been detected.
- Take preventive measures in advance for defects associated with intended and unintended changes.

The benefits of preventing defects in advance are so great that we would like you to carry out your work with an awareness of preventing defects in advance.

Regarding FMEA, FTA, DRBFM, and unintended change management discussed this time and collection of past defect cases studies, the implementation guidelines are established within the SDC division.

Please refer to the implementation guidelines for details.