

PHILIPS HEALTHCARE

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| Trainee Name: | |
| Trainee Signature: | |
| Date: | |

| Course Title | Local Course Code | Revision |
|---|--------------------------|-----------------|
| Customer Feedback Training Process for PHNA | 5100-0172 | B |

By submitting this form, I agree that I have completed the required training for this course and understand the material and the impact on my job responsibility.

Signed by 3rd Party Contractor Training Representative:

_____ Date: _____

This form is to be kept as a formal training record by the 3rd Party Contractor Agency

PHILIPS

PHILIPS

sense **and** simplicity

Customer Feedback General Awareness For Third Parties

Audience

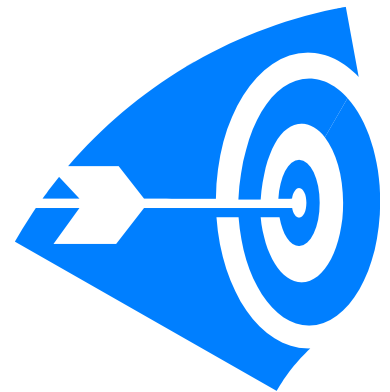
This training is for all Philips Healthcare customer facing third party agents, dealers, distributors, service and clinical applications providers.



Objectives

By the end of this course, you should:

- Understand why customer feedback is important
- Recognize a customer feedback
- Understand your role in the Philips customer feedback process
- Understand what to do when you receive a customer feedback



What is Customer Feedback?

Customer feedback is the receipt of oral, written, or electronic information about a released Philips Healthcare (PH) product, process, or service.

Customer feedback includes adverse events, or incidents, privacy or security issues, complaints, enhancements, compliments, and comments.



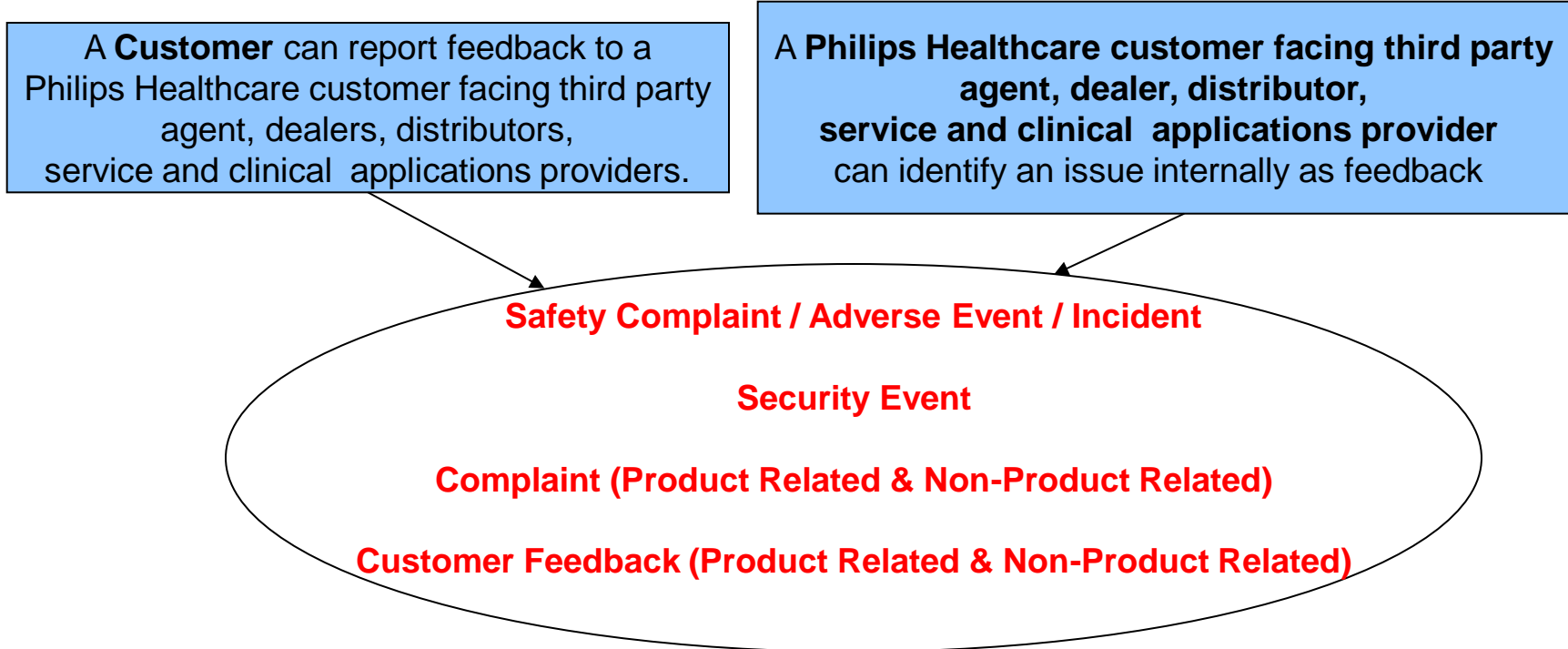
Why is Customer Feedback Important?

When we know about customer feedback, we can analyze it and respond to the feedback. This helps us:

- Assure patient and user safety
- Improve product safety
- Improve customer satisfaction
- Improve the quality of products, processes, and services
- Comply with regulatory requirements



How is Customer Feedback Received?



Other Sources of Feedback

- Internal Analysis
- Government Agencies
- Legal Notifications
- Detractors (negative results) from surveys

How Do You Recognize Customer Feedback?

If customers or patients make allegations about our products, you should consider it feedback. Examples include, but are not limited to the following situations:

- A death or injury occurred and from the information provided, it appears our device may have been associated with the death.
- A death or injury **could have** occurred
- The customer's expectations were not met.
- The customer **alleges** they had repeat service calls for the same problem.
- Our instructions for use are incorrect, unclear, or hard to follow.
- Our packaging did not adequately protect the device during shipping.



If you find out about any of these situations, even if the customer has not said anything to you or has not noticed anything, then you should also consider it customer feedback.

How Do You Recognize Customer Feedback?

So, if you hear words like:

- unsafe
- death, injury
- shock
- crushed
- moved on its own
- unresponsive
- I am not happy about
- I am not going to pay...

Then you should report this feedback.

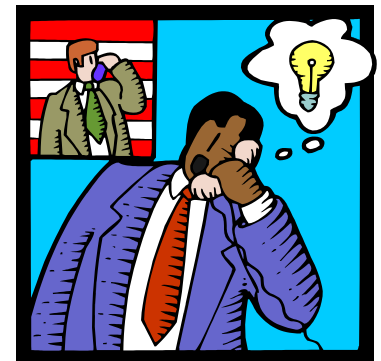


How Do You Recognize Customer Feedback?

Remember that customer feedback can be positive as well.
Feedback also includes:

- **Enhancement requests** for Philips products or sales and services activities
- **Compliments** about Philips products or sales and services activities
- **Comments** about Philips competitors and their products or sales and services activities

This type of customer feedback can give us ideas to improve our products, sales and services.



How Do You Recognize Customer Feedback?

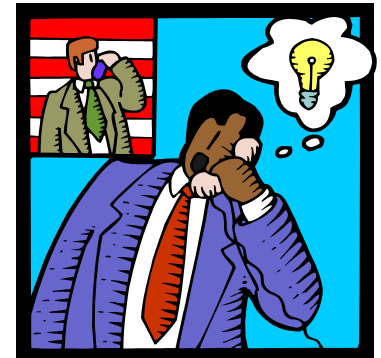
So, if you hear things like:

- It would be nice if... Or
- I really like how ...

Then you should notify a Philips Representative about the feedback or email:

USA: fprrcv.pmsna@philips.com

Canada: regulatory.canada@philips.com



What Do You Do with Customer Feedback?

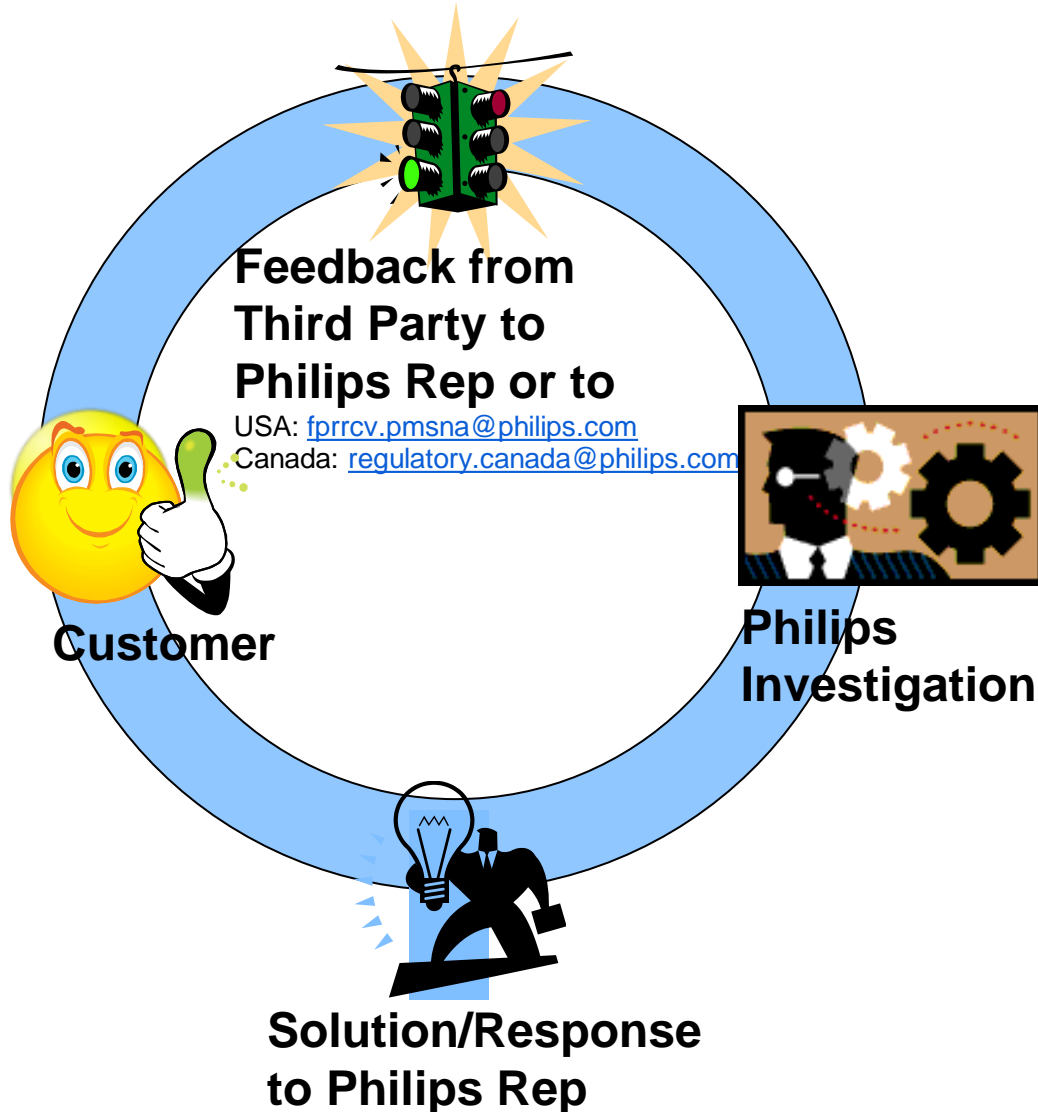
When you become aware of customer feedback, notify a Philips Representative or send email **within 24 hours**.

USA: fprrcv.pmsna@philips.com

Canada: regulatory.canada@philips.com



Feedback at Philips is a Closed Loop Process



- A **Closed Loop Process** ends where it began. This process starts with the customer giving feedback and then ends with the solution/response delivered back to the customer.
- This process simplifies how **we** will recognize and respond to Customer Feedback that will enable us to better satisfy customers' needs and ensure regulatory compliance.

Types of Customer Feedback

- Adverse event/incident
- Security event
- Complaint
- Enhancements, comments, and compliments



Adverse Event/ Incident

An **adverse event or incident** is any event that reasonably suggests that a Philips Healthcare product is associated with a death or injury; or has malfunctioned and **could be** associated with a death or injury if the malfunction were to recur.

“One of our patients died, but no alarm from the monitoring device alerted us.”

“The patient data was mixed up with another patient’s data.”

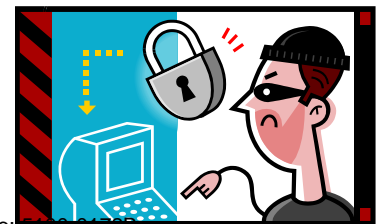
“The C-arm moved on its own and crashed on the wall.”



Security Event

A **security event** is an observable occurrence leading to any or all of the following:

- Philips Healthcare software or data that is managed by a Philips Healthcare product is suspected of being maliciously altered, misused or lost. This includes viruses, worms, hackers, etc.
- A Philips Healthcare system or component has a customer-reported security vulnerability that could result in alteration, misuse or loss.
- Confidential patient data, such as names or medical records, is at risk of disclosure
- “We received a notification about a security exposure. A hacker could potentially gain full control through remote administrator-level access.”



Complaint



A complaint is any feedback that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, security or performance of a released Philips product.*

* Source: 21 CFR 820.3 part B

Any other situation where the Philips sales and services organization is not meeting a customer's expectations is also considered a complaint.

Complaints are not requests for routine service. Routine service is any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear.

Complaint

“We have to return a lot of our transducers. They haven’t been very reliable.”

“We’ve had a service technician out 4 times to service this MRI scanner.”

“The image quality is poor.”

“We keep getting software errors.”

“My calls aren't returned promptly.”

“The price is too high.”

“The invoices are confusing.”

“It was delivered to the wrong address.”

“I can't ever talk to a real person, it's all voicemail.”

“I had to wait too long for training.”



Enhancements and Suggestions

Enhancement requests and suggestions help us improve our products and services.

“It would be nice if the IE-33 ultrasound system weighed half its current weight so it would be easier to maneuver, especially up inclines.”

“We received confirmation of a maintenance activity a week before it happened. It would be better to tell me 2 weeks before so I can plan the patient lists for the equipment.”



Compliments

Compliments are also important so that we keep or enhance a feature that a customer likes.

“We really like how the cuffs are color-coded by size. It makes it easier to find the right size.”



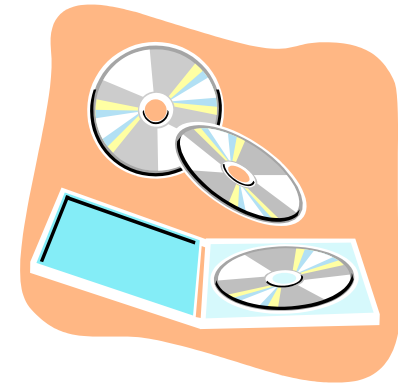
“We really like how the wires on the lead sets are color-coded.”



Compliments

Compliments aren't just for products. Sales and service receive compliments that can help other sales and service representatives be successful.

“I liked how the sales rep brought MR images on a CD that we could keep.”



Your Role in the Feedback Process

- Recognize customer feedback when you hear it.
- Notify your Philips Representative or send an email regarding customer feedback **within 24 hours** from becoming aware of the feedback.

USA: fprrcv.pmsna@philips.com

Canada: regulatory.canada@philips.com

- Provide additional information about an issue when you are asked to do so.

Thank you for your cooperation in providing customer feedback
This will enable us to help save lives, improve product safety,
and enhance customer satisfaction.

