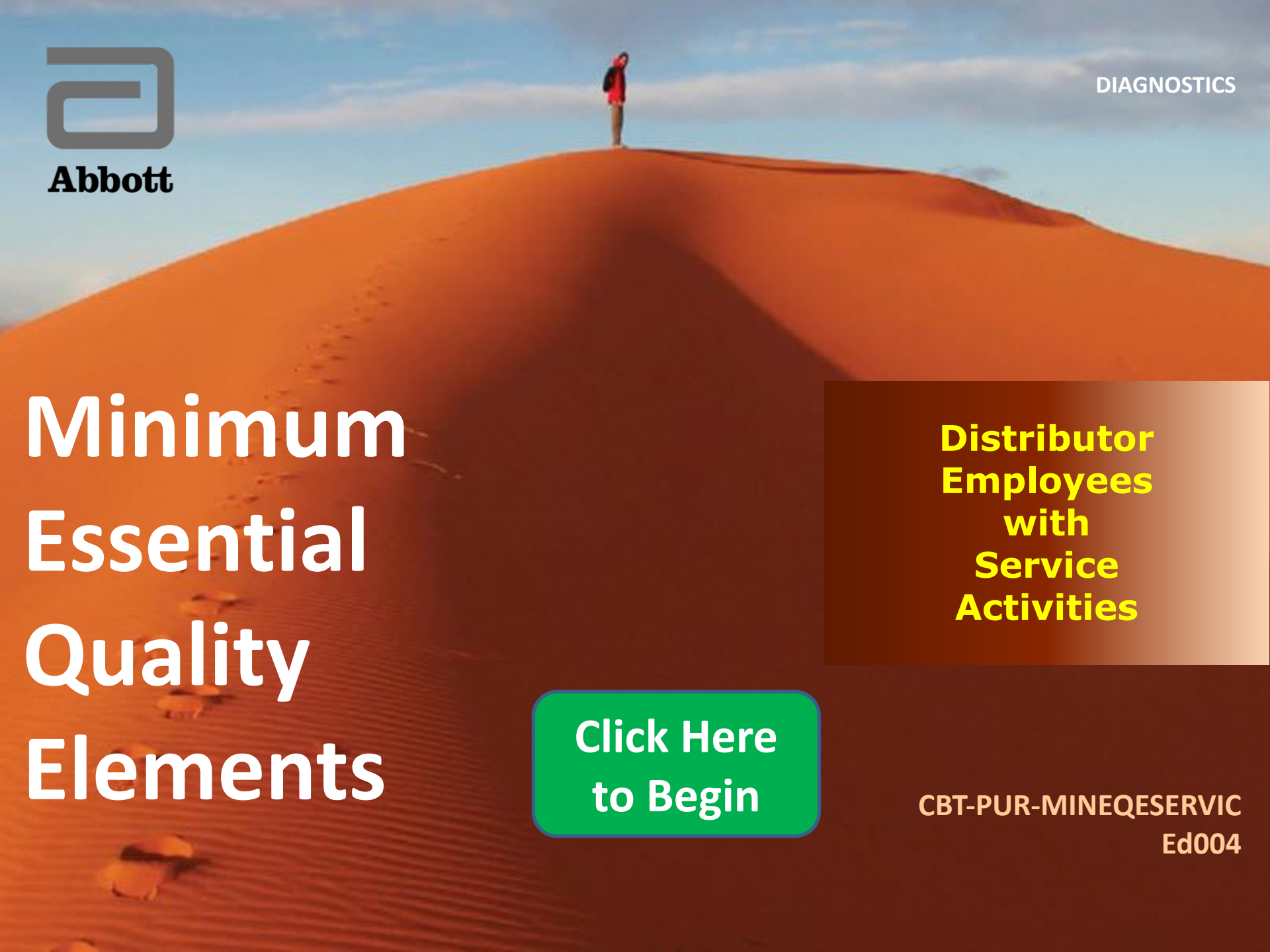

Abbott
DIAGNOSTICS
Minimum Essential Quality Elements
Distributor Employees with Service Activities
Click Here to Begin
CBT-PUR-MINEQESERVIC
Ed004

Navigation

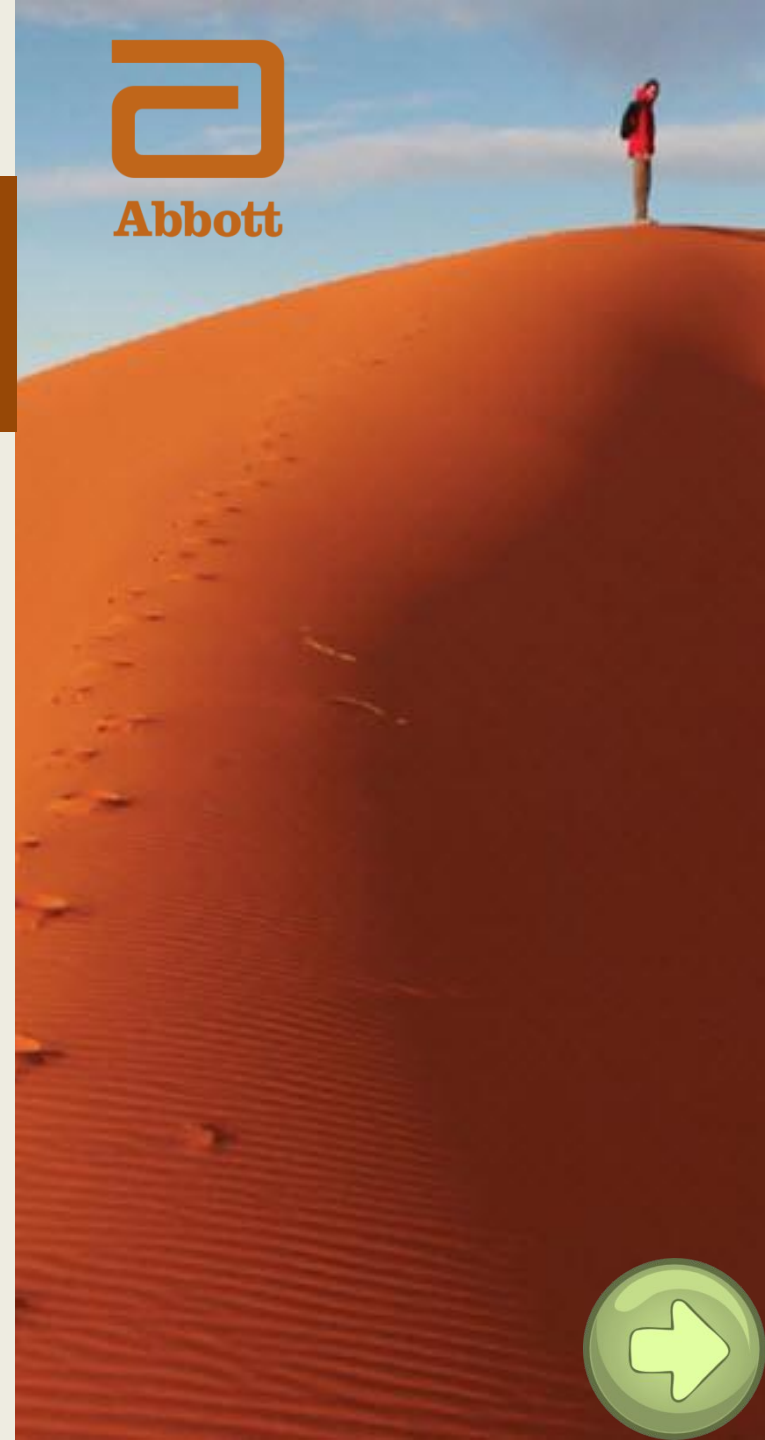
Minimum Essential Quality Elements
Navigation

Click orange arrows to go to previous slide.

Click green arrow NOW.

OVERVIEW

In this section…



Abbott

Minimum Essential Quality Elements Overview

Intended Audience

Distributor personnel with Service activities

Abbott

Minimum Essential Quality Elements Overview

The purpose of this course is to cover minimum essential elements for Distributor Employees with Service Activities.

Objectives

Minimum Essential Quality Elements Overview

Upon completion of this course, the learner should be able to:

- Recognize pREs
- Explain the importance of reporting pREs
- Describe how to communicate pREs
- Know the use and calibration of equipment & tools
- Manage inventory (parts & accessories)
- Know how the Net Promoter Score provides feedback on Customer Satisfaction
- Use only Approved Service Procedures

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Minimum Essential Quality Elements Overview

Course Units

Instructional content will be presented in 4 units:

Click #1 to begin.

1

UNIT 1

POTENTIAL REPORTABLE EVENTS

In this section…

- What are pREs?
- Why we report pREs
- How to recognize pREs
- How to report pREs

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Minimum Essential Quality Elements

Distributor Employees with Service Activities

What Is a Potential Reportable Event?

A Potential Reportable Event is an event caused by an Abbott product that leads, or could lead, to a safety issue for patients and users, including Abbott and/or Distributor employees.

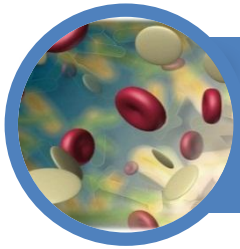
There are several Potential Reportable Event categories:

Death / Injury /

Adverse Impact to Patient

Fire / Visible Smoke

Discrepant or Questioned Patient



Exposure/Potential Exposure to Hazardous

Sample identification

Click forward arrow for examples of Potential Reportable Event categories

Potential Reportable Event Example

Death / Injury / Potential

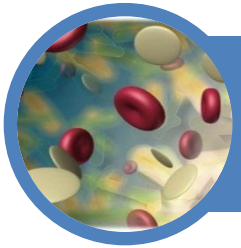
CUSTOMER STATED THAT SHE WAS STRUCK BY THE PROBE, EVEN THOUGH THE INSTRUMENT WAS IN PAUSE/STAND-BY.

Potential Reportable Event Example

Fire / Visible Smoke

WHILE TROUBLESHOOTING A POWER ISSUE ON AN INSTRUMENT, THE TSS NOTICED BLACK SOOT ON THE INSIDE OF THE INSTRUMENT AFTER REMOVING PANEL.

Potential Reportable Event Example



Exposure/Potential Exposure to Hazardous

LIQUID WASTE CONTAINER LEAKING; TECH SLIPPED AND FELL:

WASTE CONTACTED TECH'S SKIN

Potential Reportable Event Example

Adverse Impact to Patient Management

including those caused by a delay of results

CUSTOMER CONFIRMED EXCESSIVE MEDICATION ADMINISTERED DUE TO LOW GENTAMICIN RESULTS, DOCTOR NOTIFIED THEM THAT PATIENT EXHIBITED SIGNS OF TOXICITY; LAB RETESTED ORIGINAL SAMPLE AND NOW IN NORMAL RANGE.

Potential Reportable Event Example

Discrepant or Questioned Patient

A PATIENT SAMPLE WAS TESTED HIV POSITIVE ON ARCHITECT1 AND HIV NEGATIVE ON ARCHITECT2.

Potential Reportable Event Example

Sample identification Errors

ARCHITECT BARCODE MISREAD RESULTING IN RESULTS BEING INTERCHANGED FOR TWO PATIENTS.

Why Do I Have to Report pREs?

There are Legal Requirements

Communication of medical device incidents is regulated by law in many countries, and **untimely** reporting of incidents can be sanctioned.

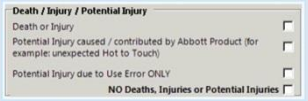
There are established timeframes to report medical events.

Why Do I Have to Report pREs?

Contd.

Health Authorities use this information to **survey potential public health problems**. Not reporting an incident may seriously damage the image and credibility of Abbott and of your company.

Abbott uses this information to identify product improvement needs.



All information regarding incidents, no matter their origin, has to be documented in the Call Management System (CMSNext).

What to Do if You Identify a pRE

ANY EMPLOYEE (not limited to service engineers) who becomes aware of an event that meets any of the criteria previously described must <u>Immediately notify one of the following:</u>

- Service Engineer
- His Manager
- Abbott Contact Person

What to Do if You Identify a pRE

Contd.

Events involving DEATH, SERIOUS INJURY or a PUBLIC HEALTH THREAT require IMMEDIATE NOTIFICATION of Abbott's <u>Medical Event Group (MEG).</u>

Call your Manager or your Abbott Contact immediately.
Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634**

Medical.Event.Group@abbott.com

Potential Public Health Threat

Potential **PUBLIC HEALTH THREATS** include events that result in imminent risk of death, serious deterioration of health or serious illness involving multiple patients.

EXAMPLE

A blood bank discovered an HIV infected blood product used for transfusion. The product has been transfused to an unknown number of recipients. The customer reported that the blood has been released with an Abbott-manufactured HIV negative result. Retesting of the original sample showed repeat reactive results for HIV and was confirmed with other test results.

In cases of death, serious injury or public health threat Abbott has to inform Health Authorities IMMEDIATELY (<48h) from the moment an Abbott employee, contractor or third party representative becomes aware of the event.

POTENTIAL REPORTABLE EVENTS SCENARIOS

In the following scenarios, you will determine whether or not each is a potential reportable event.

You will receive feedback based on your responses.

pRE Scenario 1

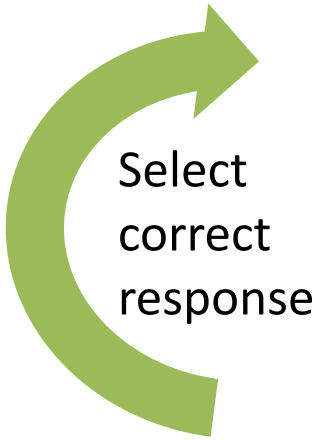
Falsely-Elevated Results

A falsely elevated Cell-Dyn Sapphire platelet result was reported on a patient. During surgery, the patient died due to intracranial bleeding.

Is this a potential reportable event?

YES

NO



pRE Scenario 1

A falsely elevated Cell-Dyn Sapphire platelet result was reported on a patient. During surgery, the patient died due to intracranial bleeding.

Correct

That is correct. An actual death occurred.

WHAT TO DO

Call your Manager or your Abbott Contact immediately.
Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

Continue

pRE Scenario 1

A falsely elevated Cell-Dyn Sapphire platelet result was reported on a patient. During surgery, the patient died due to intracranial bleeding.

Incorrect

You did not select the correct response. An actual death occurred.

WHAT TO DO

Call your Manager or your Abbott Contact immediately. Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

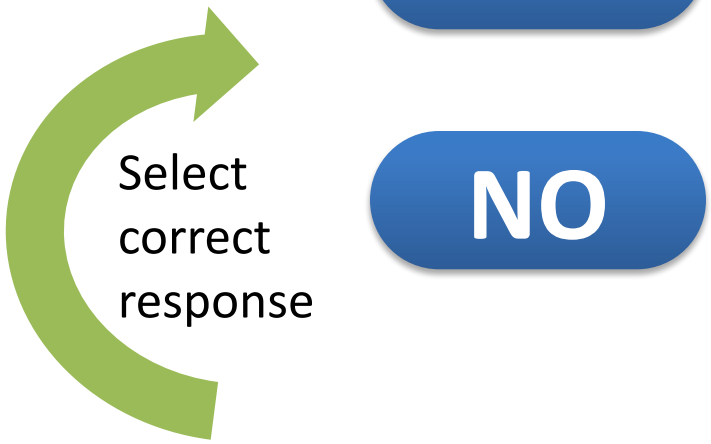
Continue

pRE Scenario 2

Superficial Cut

While replacing an ARCHITECT filter, the lab technician received a superficial cut on her left hand.

Is this a potential reportable event?



pRE Scenario 2

While replacing an ARCHITECT filter, the lab technician received a superficial cut on her left hand.

Correct

That is correct. An actual injury occurred.

WHAT TO DO

Call your Manager or your Abbott Contact immediately.
Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

Continue

pRE Scenario 2

While replacing an ARCHITECT filter, the lab technician received a superficial cut on her left hand.

Incorrect

You did not select the correct response. An actual injury occurred.

WHAT TO DO

Call your Manager or your Abbott Contact immediately. Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

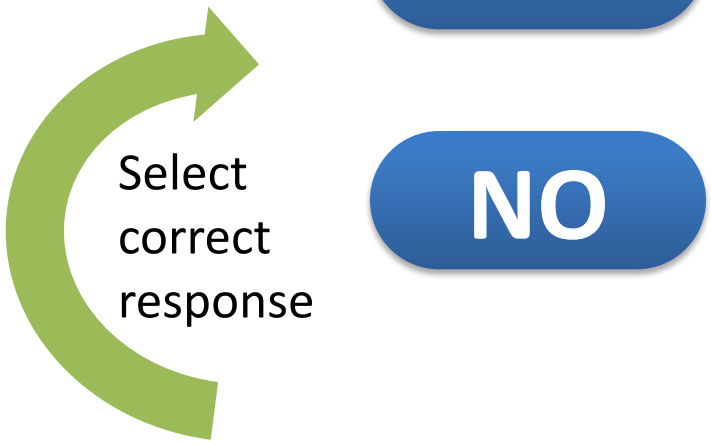
Continue

pRE Scenario 3

ARCHITECT i2000 Lid

The ARCHITECT i2000 lid was not properly fixed as it is supposed to be during maintenance activities. It fell while a Service Engineer was performing troubleshooting. No one was injured.

Is this a potential reportable event?



pRE Scenario 3

The ARCHITECT i2000 lid was not properly fixed as it is supposed to be during maintenance activities. It fell while a Service Engineer was performing troubleshooting. No one was injured.

Correct

That is correct. Although the lid was not fixed as it should be, no injury occurred.

WHAT TO DO

No further action is required.

Continue

pRE Scenario 3

The ARCHITECT i2000 lid was not properly fixed as it is supposed to be during maintenance activities. It fell while a Service Engineer was performing troubleshooting. No one was injured.

Incorrect

You did not select the correct response. Although the lid was not fixed as it should be, no injury occurred.

WHAT TO DO

No further action is required.

Continue

pRE Scenario 4

Sparks & Smoke

A customer reported sparks and smoke coming out of an ARCHITECT i2000 although no one was injured.

Is this a potential reportable event?

YES

NO

Select correct response

pRE Scenario 4

A customer reported sparks and smoke coming out of an ARCHITECT i2000 although no one was injured.

Correct

That is correct. An injury could have occurred.

WHAT TO DO

Call your Manager or your Abbott Contact immediately. Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

Continue

pRE Scenario 4

A customer reported sparks and smoke coming out of an ARCHITECT i2000 although no one was injured.

Incorrect

You did not select the correct response. An injury could have occurred.

WHAT TO DO

Call your Manager or your Abbott Contact immediately. Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

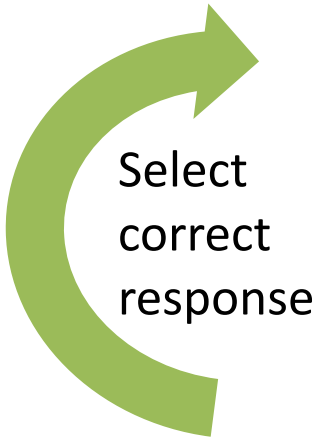
Continue

pRE Scenario 5

Invalid Results

The Cell-Dyn in a customer's lab has been unable to generate valid results for platelets for 2 days; Field Service has been dispatched.

Is this a potential reportable event?



YES

NO

pRE Scenario 5

The Cell-Dyn in a customer's lab has been unable to generate valid results for platelets for 2 days; Field Service has been dispatched.

Correct

"NO" is right! There was NO adverse impact to patient management. The customer did not report that patient management was impacted.

WHAT TO DO

No further action is required.

Continue

pRE Scenario 5

The Cell-Dyn in a customer's lab has been unable to generate valid results for platelets for 2 days; Field Service has been dispatched.

Incorrect

You did not select the correct response. There was NO adverse impact to patient management. The customer did not report that patient management was impacted.

WHAT TO DO

No further action is required.

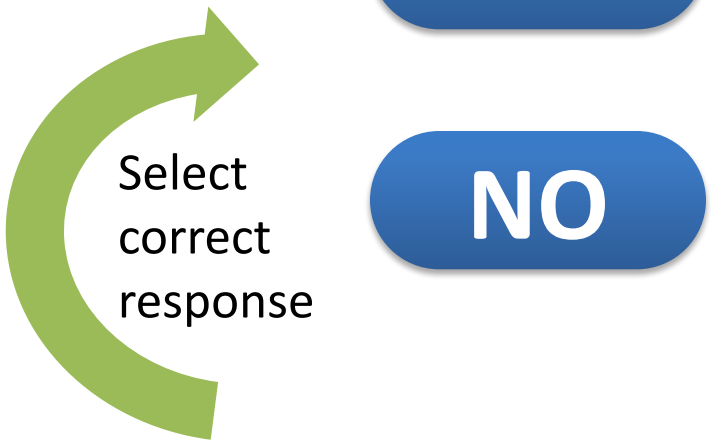
Continue

pRE Scenario 6

Your neighbor complains about an Abbott tumor marker assay generating discrepant results.

Discrepant Results

Is this a potential reportable event?



pRE Scenario 6

Your neighbor complains about an Abbott tumor marker assay generating discrepant results.

Correct

"Yes" is correct. Discrepant results could lead to an adverse impact to patient management.

WHAT TO DO

Call your Manager or your Abbott Contact immediately. Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

Continue

pRE Scenario 6

Your neighbor complains about an Abbott tumor marker assay generating discrepant results.

Incorrect

You did not select the correct response. Discrepant results could lead to an adverse impact to patient management.

WHAT TO DO

Call your Manager or your Abbott Contact immediately. Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

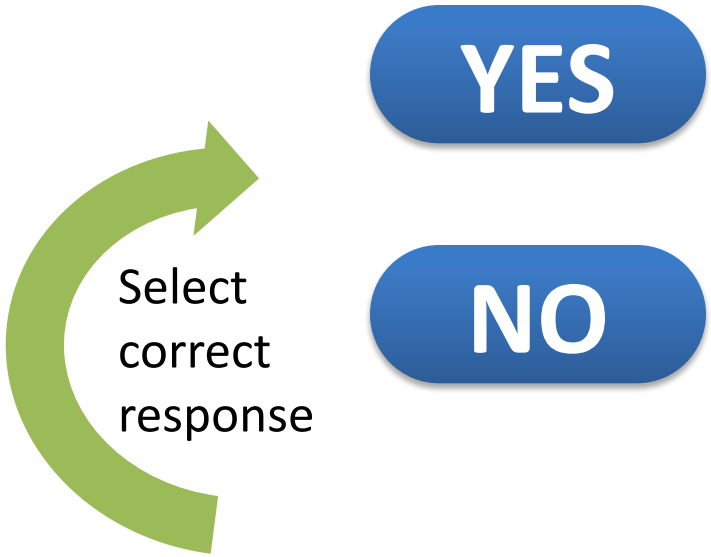
Continue

pRE Scenario 7

Sample Identification Error

During a customer visit the customer mentioned that an error in sample identification occurred. After discussing the issue the customer even indicated that this error resulted in incorrect result assignment for a patient.

Is this a potential reportable event?



pRE Scenario 7

During a customer visit the customer mentioned that an error in sample identification occurred. After discussing the issue the customer even indicated that this error resulted in incorrect result assignment for a patient.

Correct

"Yes" is correct. Incorrect sample identification led to adverse impact to patient management.

WHAT TO DO

Call your Manager or your Abbott Contact immediately.
Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

Continue

pRE Scenario 7

During a customer visit the customer mentioned that an error in sample identification occurred. After discussing the issue the customer even indicated that this error resulted in incorrect result assignment for a patient.

Incorrect

You did not select the correct response. Incorrect sample identification led to adverse impact to patient management.

WHAT TO DO

Call your Manager or your Abbott Contact immediately. Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

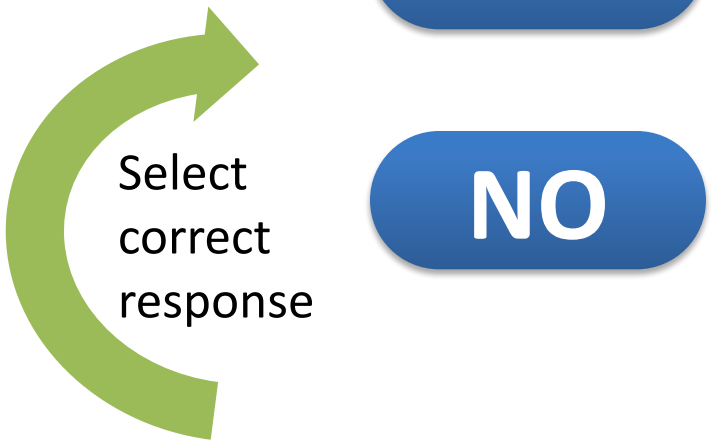
Continue

pRE Scenario 8

User Report to Authorities

An angry customer comments he has reported on discrepant results with an Abbott assay to the Health Authorities.

Is this a potential reportable event?



pRE Scenario 8

An angry customer comments he has reported on discrepant results with an Abbott assay to the Health Authorities.

Correct

"Yes" is correct. A safety issue may be involved.

WHAT TO DO

Call your Manager or your Abbott Contact immediately.
Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

Continue

pRE Scenario 8

An angry customer comments he has reported on discrepant results with an Abbott assay to the Health Authorities.

Incorrect

You did not select the correct response. A safety issue may be involved.

WHAT TO DO

Call your Manager or your Abbott Contact immediately.
Alternatively, you can call Medical Event Group (MEG) directly @ **+1 224 668 1634.**

- **If you have access to CMSNext:** Enter a service ticket in CMSNext and flag for the correct pRE category.
- **If you do not have access to CMSNext:** Report to your Area Call Center Hub or to your Manager.

Continue

End of Unit 1

This concludes Unit 1, "Potential Reportable Events"

Click #2 to begin next unit.

2

UNIT 2

CALIBRATION OF SERVICE TOOLS

In this unit…

- Measuring & Test Equipment
- Identifying Calibrated Equipment
- Calibration Intervals
- Using Only Calibrated Tools

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Minimum Essential Quality Elements

Distributor Employees with Service Activities

Measuring & Test Equipment

Test Equipment Used to Service Abbott Instruments

multimeter

thermometer

These are classified as non-critical, requiring calibration

Measuring and test equipment used during installation, service and maintenance must be:

traceable

calibrated

Physical Identification of Calibrated Equipment

What you're looking for on every piece of calibrated equipment

- unique identifier for the measurement device
- calibration date
- calibration due date
- limitations, if applicable
- signature + date of person performing calibration

Calibration Intervals

Calibration intervals may be based on:

Equipment Manufacturer's Recommendations

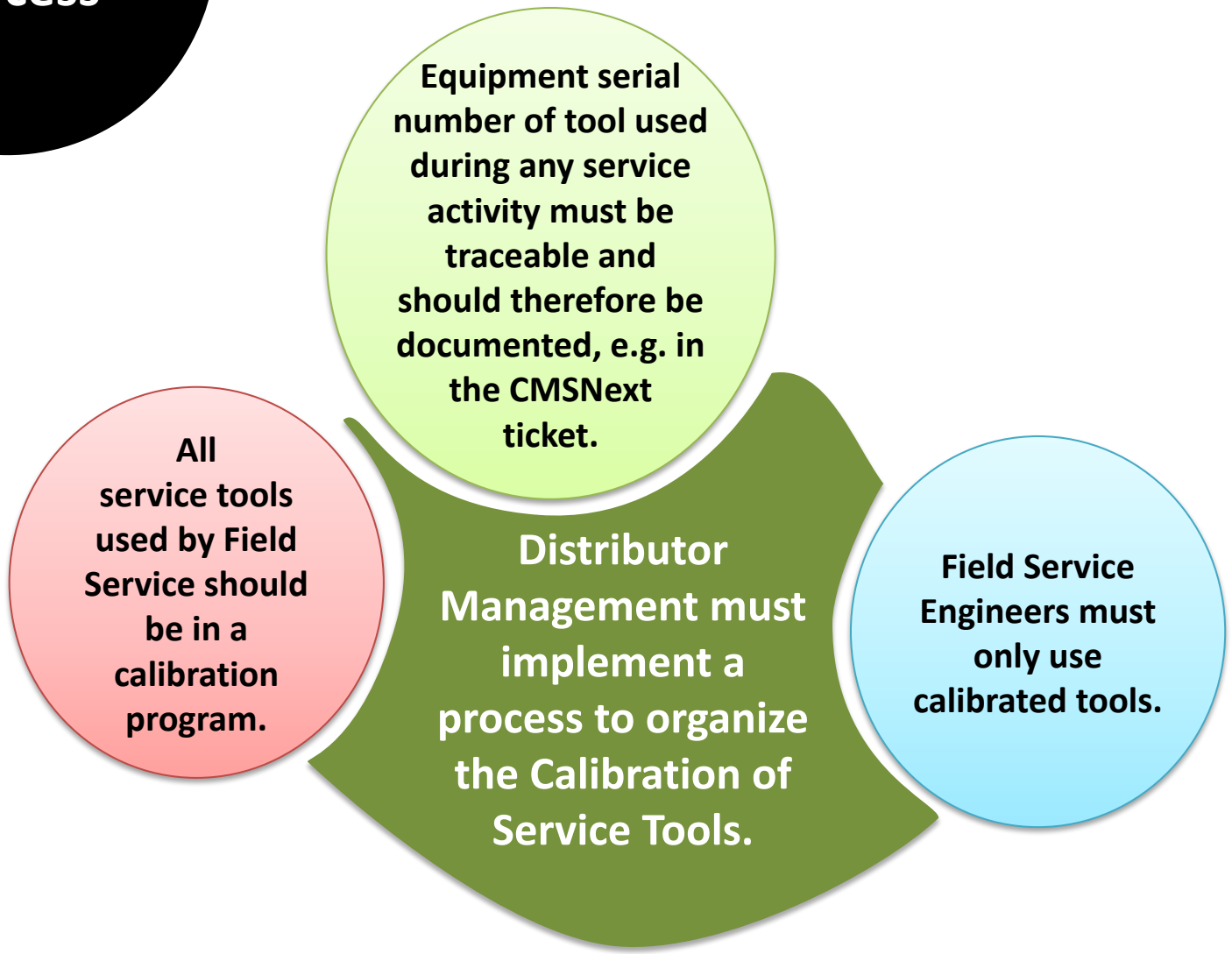
- usually annually

Engineering Expertise

- If resulting in calibration interval > 1 year, written justification approved by Abbott is required

Records of the calibration must be kept

Calibration Process



End of Unit 2

This concludes Unit 2, "Calibration of Service Tools"

Click #3 to begin next unit.

UNIT 3

INVENTORY MANAGEMENT

In this unit…

- Spare Parts Depot
- Parts return/defective parts destruction/defacing Abbott logos
- Process for quality holds-how we handle issues for spare parts
- Biosafety

Instrument Spare Parts

There are spare parts, accessories or training supplies stored in a closet, room or larger area.

Click photo on the right to learn about minimum Product Control necessities.

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Minimum Essential Quality Elements
Unit 3: Inventory Management

How to Manage Used Parts

Click on each blue button for details about to manage used parts.

1. All used spare parts and accessories have to be considered contaminated

Click for Step 1

2. Destruction by an authorized company

3. Return to centralized Area Parts Return Center

4. Instrument Parts Return

How to Manage Used Parts

Contd.

1. All used spare parts and accessories have to be considered contaminated
2. Destruction by an authorized company
3. Return to centralized Area Parts Return Center
4. Instrument Parts Return

All used spare parts and accessories have to be considered contaminated

Perform decontamination and/or packaging including labeling per local legislation before shipping to determined destinations.

Always adhere to Biosafety requirements.

Click for Step 2

How to Manage Used Parts

Contd.

1. All used spare parts and accessories have to be considered contaminated
2. Destruction by an authorized company
3. Return to centralized Area Parts Return Center
4. Instrument Parts Return

Destruction by an authorized company

Destruction certificate is required.

Click for Step 3

How to Manage Used Parts

Contd.

1. All used spare parts and accessories have to be considered contaminated

2. Destruction by an authorized company

3. Return to centralized Area Parts Return Center

Return to Centralized Area Parts Return Center

- Failure Analysis Investigation
- Repair of the Parts for return to inventory
- Parts for destruction may also be returned to Area Parts Return Center

4. Instrument Parts Return

Click for Step 4

How to Manage Used Parts

Contd.

1. All used spare parts and accessories have to be considered contaminated
2. Destruction by an authorized company
3. Return to centralized Area Parts Return Center
4. Instrument Parts Return

Instrument Parts Return

- Wipe down surface with disinfectant
- Drain items with contaminated fluid pathways, e.g. pumps; disinfect as possible.
- Place the part for return in a plastic bag and close the bag using a tape or rubber band. In case of residual moisture in the part that could leak out, place some absorbent material, such as paper towel, in the bag with the part(s).
- Fill out a “Material Return/Repair“ tag or equivalent and attach it to the bag with the part(s).
- Label the bag as „Used parts – Handle as “Contaminated.“
- Place the bag into a cardboard box and ship it to the appropriate site.

Click to continue

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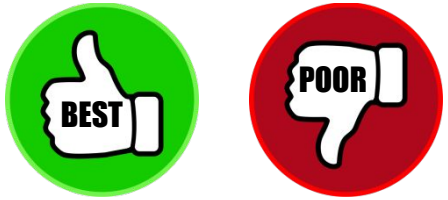
Minimum Essential Quality Elements
Unit 3: Inventory Management

Best Practices vs. Poor Practices

INSTRUMENT SPARE PARTS



The next few slides will provide information on these best repair practices you should be following.

- Ordering Parts for Repair
- Instrument Waste Lines
- Damaged Cables
- Guiding Customers through a Repair
- Phone Fixes
- System Files

Best Practices vs. Poor Practices

Ordering Parts for Repair

Order only approved parts for use in repair.

GPPM, Global Product Part Master, contains all approved parts.

purchasing from a local store

Best Practices vs. Poor Practices

Instrument Waste Lines

Maintain integrity of the instrument's one waste line.

modifying the waste drainage to 2 waste line exits

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Best Practices vs. Poor Practices

Minimum Essential Quality Elements
Unit 3: Inventory Management

Damaged Cables

Order and replace damaged cables.

soldering a broken cable

Best Practices vs. Poor Practices

Guiding Customers through a Repair

Guiding the customer through the repair including required verification procedures.

Send a customer an internal use only procedure (for example, from the service manual).

Best Practices vs. Poor Practices

Phone Fixes

Instruct customers on phone fixes only for those actions allowed for customers by servicing documents.

Perform a phone fix where the customer is instructed to perform an action not allowed by servicing documents (e.g., temperature adjusted even though procedure specifically states not to adjust).

Best Practices vs. Poor Practices

System Files

Maintains system file at original factory settings.

Modify a system file to change system/product functionality or steps.

Parts on Quality Hold

INSTRUMENT SPARE PARTS

Quality Hold released for specific part numbers

Do not use / install any parts / accessories on Quality Hold

Upon receipt of Quality Hold Communication from Abbott, all distributor employees must be informed.

Follow communicated instructions

- Immediately segregate parts/accessories on Quality Hold
- Return parts/accessories clearly labeled to spare parts depot or warehouse.

Biosafety Practices in the Laboratory

The next several slides contain information on biosafety practices in the laboratory.

You will learn about:

Biosafety Level 3 or 4 Laboratory

Personal Protective Equipment

Cuts or Sores

Washing Hands

Eating/Drinking/ Smoking

No Mouth Pipetting

Use Controls and Standards

Working with Probes

Discarding Contaminated Material

Contaminated Tools

Bottled or Compressed Air

Biosafety Practices in the Laboratory

Contd.

Biosafety Level 3 or 4 Laboratory

Do not enter any Biosafety level 3 or level 4 laboratory without prior approval by your Management.

- Level 3: clinical or research involving work with agents that can cause a serious disease, e.g. Mycobacterium tuberculoses, B. Anthracis, SARs, West Nile Virus
- Level 4: Max. Containment facility used for research with dangerous agents that pose risk of life, e.g. Smallpox, Hendra/Nipah virus, Lassa fever virus, Marburg virus, Congo-Crime Hemorrhagic fever.

Personal Protective Equipment

Wear appropriate personal protective equipment.

Check laboratory signage for proper PPE.

Cuts or Sores

Cover any cuts or sores on your hands or forearms, with a waterproof bandage.

Biosafety Practices in the Laboratory

Contd.

Washing Hands

Wash hands after removing your gloves, and when leaving the laboratory area.

Biosafety Practices in the Laboratory

Contd.

Eating / Drinking / Smoking

Do not eat, drink, smoke, apply cosmetics or lip balm, or handle contact lenses in the laboratory area.

Biosafety Practices in the Laboratory

Contd.

No Mouth Pipetting

Do not pipette by mouth.

Do not touch your mouth with your hands or contaminated objects.

Biosafety Practices in the Laboratory

Contd.

Use Controls and Standards

Avoid running customer samples on the instrument.

Use controls and standards.

Biosafety Practices in the Laboratory

Contd.

Working with Probes

Use extreme caution when working around probes.

Rinse the probes with buffer or water or wipe the probe with disinfectant prior to handling it.

Discarding Contaminated Material

Discard all contaminated material into the appropriate biohazard waste system in the lab.

Biosafety Practices in the Laboratory

Contd.

Contaminated Tools

Disinfect contaminated tools prior to returning them to your tool kit.

Bottled or Compressed Air

Never use bottled or compressed air to clean instrument surfaces in labs where they are working with respiratory transmissible agents such as influenza, SARs, etc.

Handling Biosafety Situations

Minimum Essential Quality Elements
Unit 3: Inventory Management

Click the blue button to learn how to handle this biosafety situation.

- Handling Electronic Equipment in the Laboratory
- Handling of Accidental Exposure
- Decontamination and Disinfection Practices

Handling Electronic Equipment in the Laboratory

- Computers that must be used in the laboratory environment should have the keyboard protected if you will be wearing gloves and handling the instrument, reagents, etc. You can do this by using a plastic keyboard protector, plastic bag or plastic wrap to cover the unit while you are working. Dispose of plastic bags/wrap along with the laboratory's other contaminated waste. Wipe down plastic keyboard with disinfectant.
- Cell phones, when used in the lab, must be wiped down with a disinfectant
- Comply with established laboratory practices, e.g., some facilities might require decontamination of units, even if you were not wearing gloves at the time of use.

Handling Biosafety Situations

Contd.

Click the blue button to learn how to handle this biosafety situation.

Handling Electronic Equipment in the Laboratory

Handling of Accidental Exposure

Decontamination and Disinfection Practices

Handling Biosafety Situations

Handling of Accidental Exposure

- Wash or rinse the affected area immediately.
- If exposure to any specimen/samples, make sure that they are identified and retained for further testing.
- Seek medical attention immediately at the nearest hospital or clinic. Provide the physician with information on the type of material processed.
- A vaccination against the most common agents, e.g. Hepatitis B are recommended.

Handling Biosafety Situations

Contd.

Click the blue button to learn how to handle this biosafety situation.

Handling Electronic Equipment in the Laboratory

Handling of Accidental Exposure

Decontamination and Disinfection Practices

Handling Biosafety Situations

Decontamination and Disinfection Practices

- Decontaminate instruments as specified in the respective system‘s Service and Support Manual.
- For transportation, remove all tubing, reagents; empty and disinfect waste containers.
- Use extreme caution when handling the probe or any other sharps.

Wear Biosafety Protective Equipment

End of Unit 3

This concludes Unit 3, "Inventory Management"

Click #4 to begin next unit.

UNIT 4

MISCELLANEOUS

In this unit…

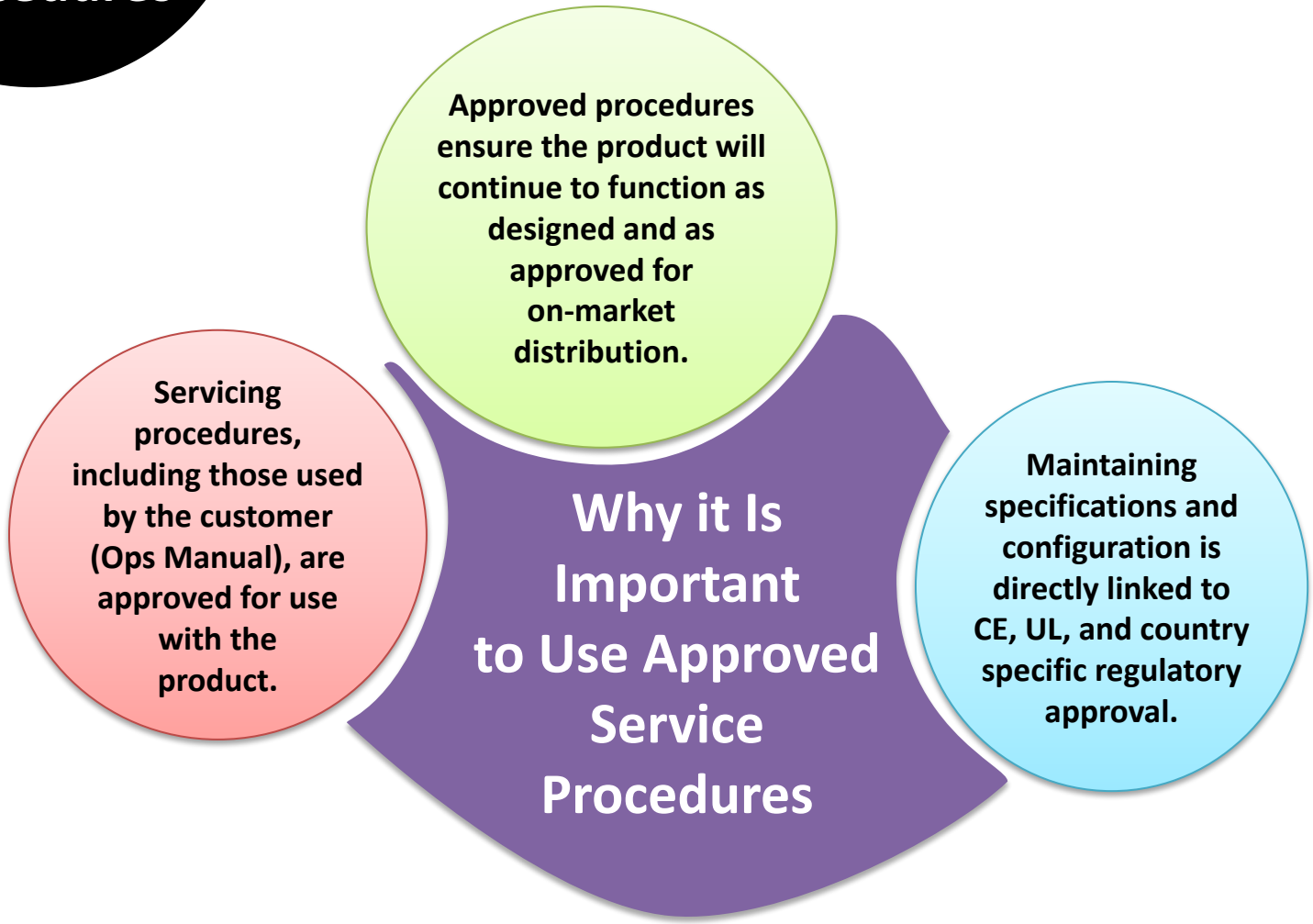
- Approved Service Procedures
- Net Promoter Score

Abbott

Minimum Essential Quality Elements

Distributor Employees with Service Activities

Approved Service Procedures



Why It's Important to Use Approved Service Procedures

What Not To Do

- DO NOT deviate from approved procedures
- DO NOT complete only a portion of an approved procedure unless specifically allowed by the procedure (for example, PM checklist with natural break points)
- DO NOT develop your own repair procedures
- DO NOT use unapproved parts/product
- DO NOT modify approved parts/product in anyway
- DO NOT use repair procedures that you may have been trained on in prior jobs if we do not have a procedure that allows the same repairs

Approved Service Procedures

Contd.

KNOWLEDGE CHECK

On the next slide, there is a knowledge check question about service procedures. You will be given feedback based on your answer.

Knowledge Check

While at a customer site, a Field Service Engineer determined that the Architect i2000SR side cover would not fit. The customer wanted the installation to be completed to meet their Test-of-Record target date.

To complete the instrument installation, the FSE determined that he could enlarge the opening within the cover to allow accessibility to the motor. This minor change would not require any additional changes or modifications to other aspects of the instrument and would allow him to complete the installation on time.

How should the Field Service Engineer proceed?

(Click on correct response)

- Do not modify the cover but rather complete the installation without the cover. Allow customer to proceed with test-of-record activities.
- Proceed with modifying the cover, ensuring all verifications are completed to demonstrate successful installation. Allow customer to proceed with test-of-record activities.
- Order a new cover. Continue with other installation activities. Complete installation upon receipt of replacement part.

KNOWLEDGE CHECK

While at a customer site, a Field Service Engineer determined that the Architect i2000SR side cover would not fit. The customer wanted the installation to be completed to meet their Test-of-Record target date.

To complete the instrument installation, the FSE determined that he could enlarge the opening within the cover to allow accessibility to the motor. This minor change would not require any additional changes or modifications to other aspects of the instrument and would allow him to complete the installation on time.

Correct

That's right! It is unacceptable to modify a part in any manner unless specifically allowed by the servicing procedure. Successful completion of verification procedures does not justify the modification made.

Continue

KNOWLEDGE CHECK

While at a customer site, a Field Service Engineer determined that the Architect i2000SR side cover would not fit. The customer wanted the installation to be completed to meet their Test-of-Record target date.

To complete the instrument installation, the FSE determined that he could enlarge the opening within the cover to allow accessibility to the motor. This minor change would not require any additional changes or modifications to other aspects of the instrument and would allow him to complete the installation on time.

Incorrect

You did not select the correct response. It is unacceptable to modify a part in any manner unless specifically allowed by the servicing procedure. Successful completion of verification procedures does not justify the modification made.

Continue

CMSNext

WHAT IS IT?

CMSNext is Abbott's Call Management System to document routine service activities to submit product issues for investigation and pREs for evaluation and authority reporting.

WHO USES IT?

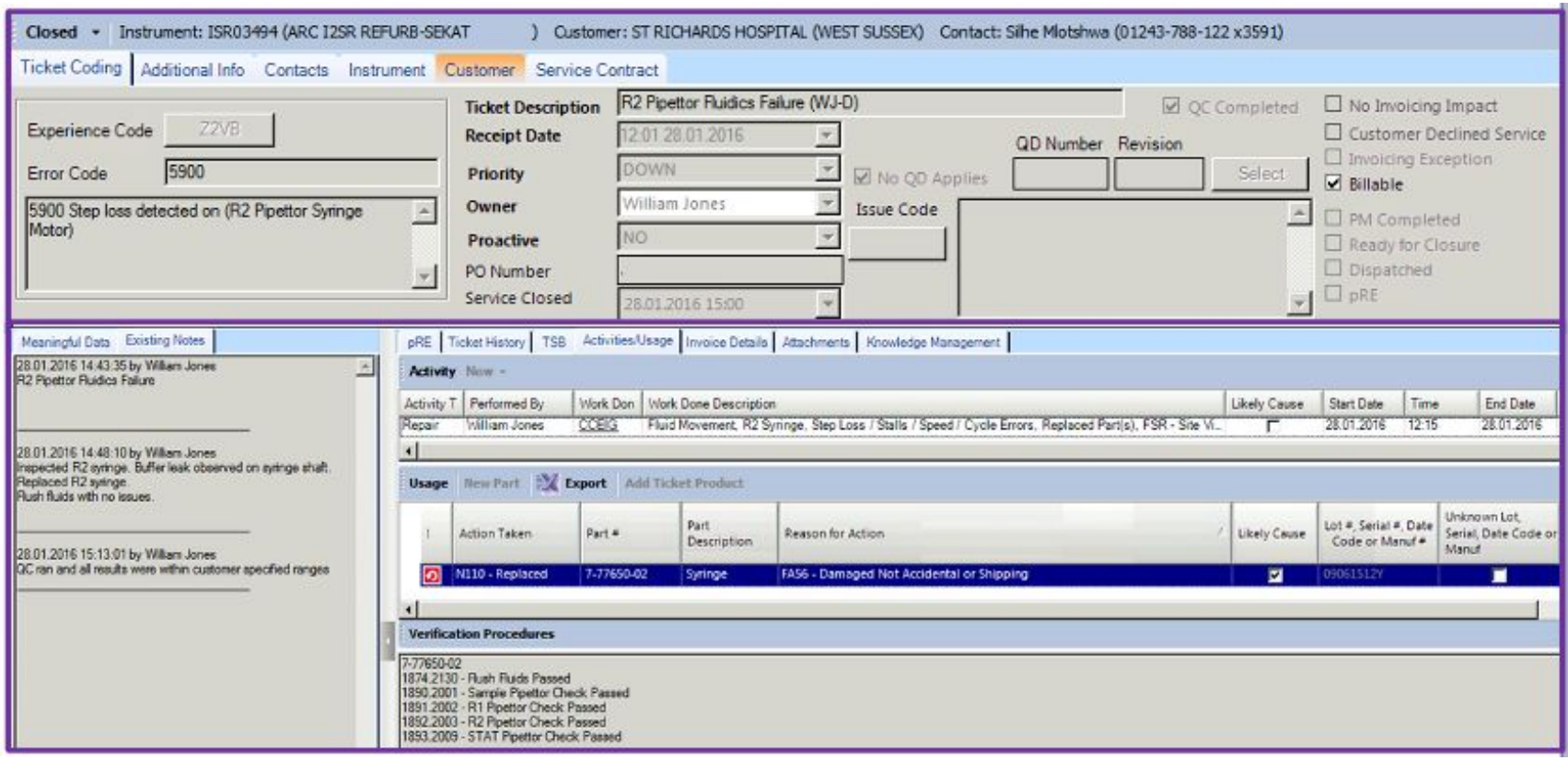
CMSNext is used primarily by Service & Support personnel but other main users are Product Quality, Medical Events, Logistics, Distributors, IT support and third party service & support providers.

All service-related customer contacts must be registered in CMSNext.

- From service tickets logged in CMSNext, a determined rate of customers is picked for NPS interviews.

Click Here to View an Example of a Logged Service Ticket

Example of Logged Service Ticket



Net Promoter Score

What Is Customer Loyalty?

Customer Loyalty is…

"Share of wallet, mind, and mouth."

- *Richard D. Hanks, former EVP and Corporate Officer, Marriott*

Loyalty is more than customer satisfaction. Loyalty involves an emotional commitment to a brand.

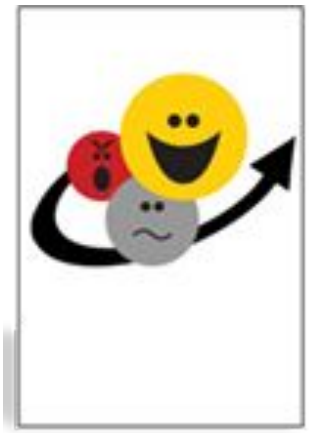
It typically has an attitude component ("I feel good about this product") and a behavior component ("I will keep buying it").

Attitudes are important because re-purchase alone doesn't always mean a customer is emotionally invested.

Net Promoter Score

Contd.

What Is the Net Promoter System®?



The Net Promoter System® is based on a score which provides a measure of customer loyalty by asking one simple question:

On a scale of 0 to 10, how likely are you to recommend Abbott to a colleague or friend?

0-6	7-8	9-10
Extremely unlikely		Extremely likely

Net Promoter Score

Contd.

Customer Loyalty Profiles

Based on their responses, customers are grouped into one of these 3 customer profiles:

Promoters are customers who give us a “9” or “10” and are loyal enthusiasts who keep buying from us and urge their friends to do the same.

Passives are customers who give us a “7” or “8” and are satisfied but unenthusiastic about the product or service and can be easily influenced to switch to a competitor.

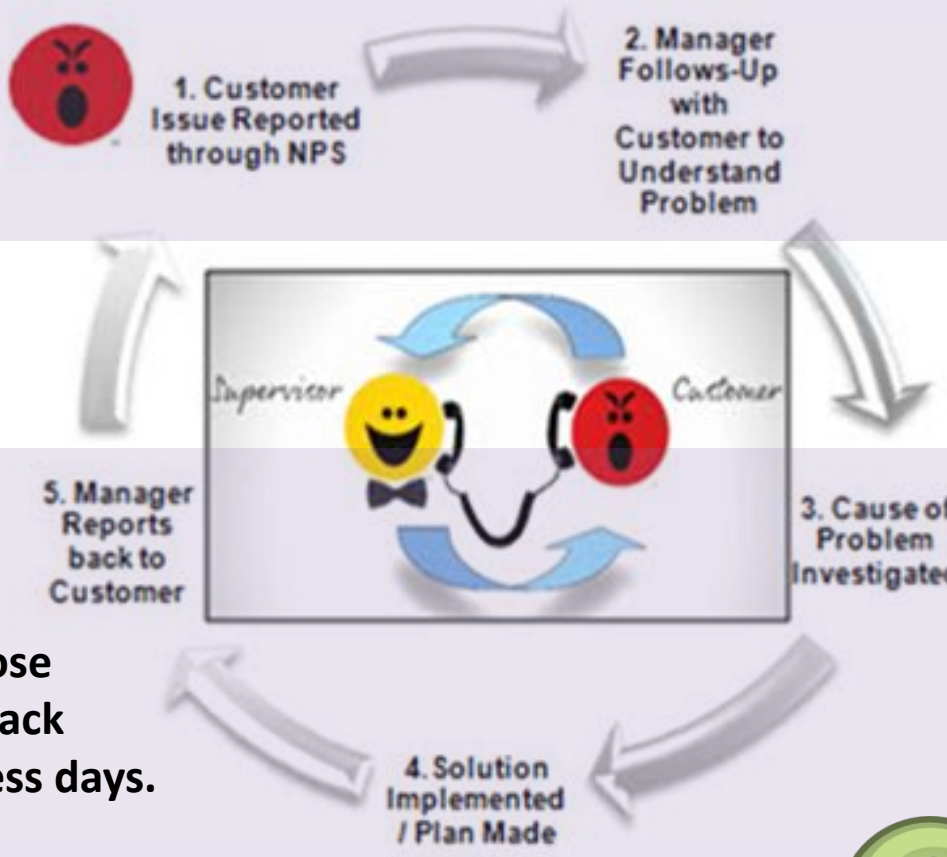
Detractors are customers who give us responses from “0 – 6” because they are unhappy with the product or service. These customers are likely to speak badly about the company to colleagues and friends, and will likely give their business to another supplier.

Net Promoter Score

Contd.

At ADD, we take customer concerns very seriously.

Once a customer reports an issue through the NPS system, a manager follows up with the customer regarding the issue within 72 hours.



ADD conducts an internal investigation of every customer reported issue, and we aim to close all issues and report resolution back to the customer within 20 business days.

Net Promoter Score

Contd.

Net Promoter Score Summary

Remember!

1. Customer loyalty is a key component of our organization's vision.

2. Net Promoter Score (NPS) acts as a barometer to measure customer loyalty and our potential for growth.

3. The Golden Rule is at the center of the Net Promoter® System and the core principle for creating loyal customers.

4. At Abbott, we all come to work every day to serve our external customers who are lab personnel and, ultimately, the patients. It is also important to remember that internal customers matter, too.

5. Every job impacts customer loyalty.

End of Unit 4

This concludes Unit 4, "Miscellaneous"

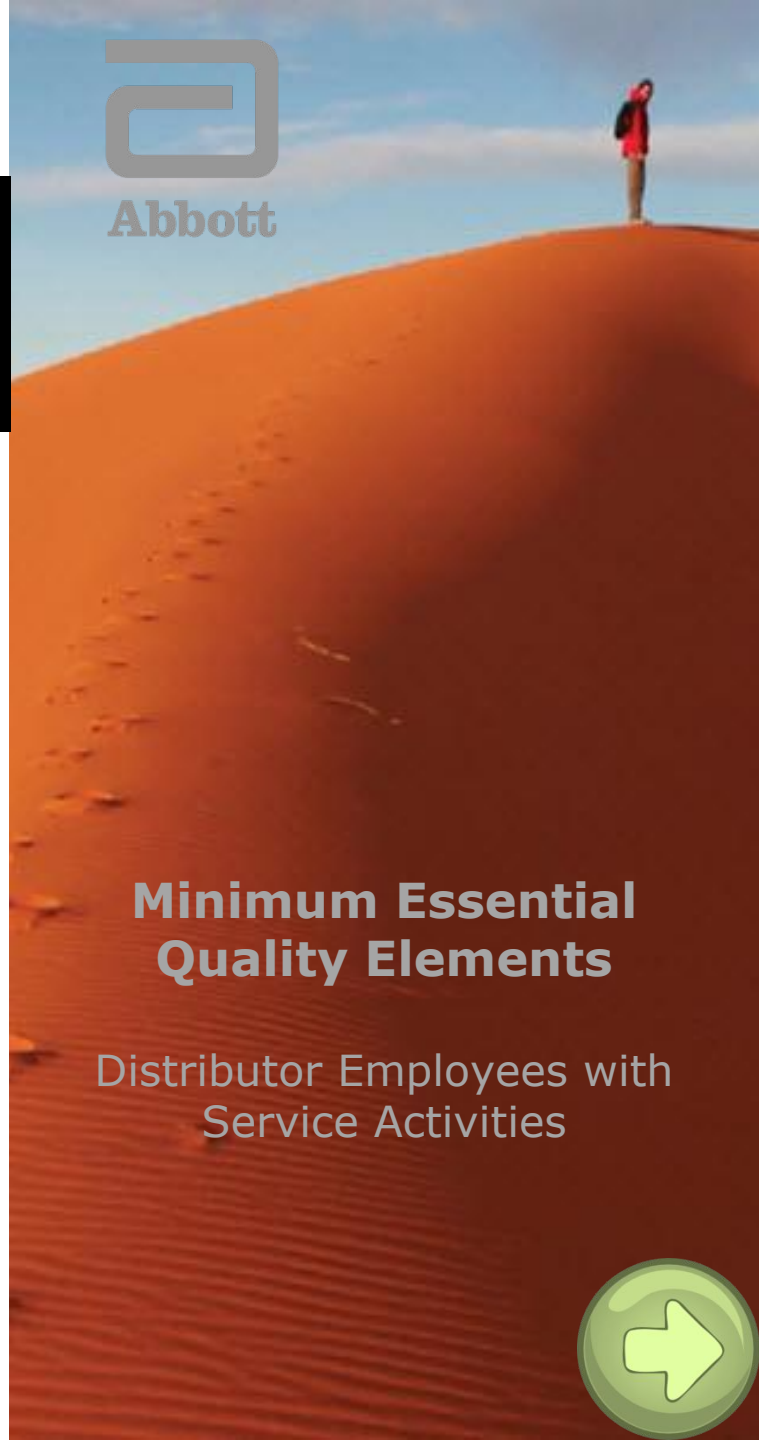
Click #5 to begin next unit.

UNIT 5

KNOWLEDGE CHECK

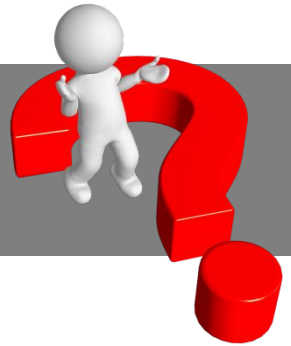
In this unit…

4 knowledge check questions based on what you have learned in this course. You will receive feedback based on your responses.



Knowledge Check

Which of these are a Category of Potential Reportable Events?

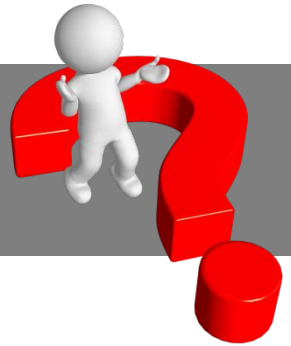


Question 1

Select all responses that apply

- A. Death, Injury, Potential Injury — THAT'S CORRECT!
- B. Adverse Impact to Patient Management — THAT'S CORRECT!
- C. Net Promoter Score — THAT'S INCORRECT
- D. Discrepant or Questioned Patient Results — THAT'S CORRECT!
- E. Sample Identification Error — THAT'S CORRECT!

Knowledge Check



Question 2

Select correct response

Parts for Failure Analysis Investigation, Repair of Parts for Return to Inventory and also Parts for Destruction are supposed to be returned to your centralized Area Parts Return Center.

TRUE

FALSE

Knowledge Check 2

Parts for Failure Analysis Investigation, Repair of Parts for Return to Inventory and also Parts for Destruction are supposed to be returned to your centralized Area Parts Return Center.

Correct

That's right! Return these parts to your centralized Area Parts Return Center.

Continue

Knowledge Check 2

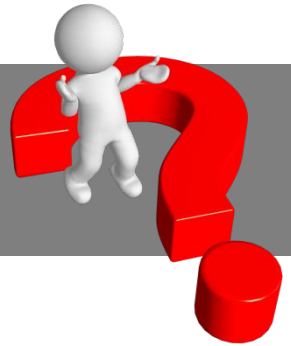
Parts for Failure Analysis Investigation, Repair of Parts for Return to Inventory and also Parts for Destruction are supposed to be returned to your centralized Area Parts Return Center.

Incorrect

You did not select the correct response. You must return these parts to your centralized Area Parts Return Center.

Continue

Knowledge Check



Question 3

Select correct response

You are preparing your tool box for an upcoming i2000SR installation next week and you discover that the calibration date of your Multimeter will have been expired by the scheduled installation date.
What will you do?

- Return the Multimeter to your head office and wait until you receive the replacement Multimeter with valid calibration
- Use the Multimeter with the expired calibration date because the calibration due date expired only 4 days before the scheduled installation.

Knowledge Check 3

You are preparing your tool box for an upcoming i2000SR installation next week and you discover that the calibration date of your Multimeter will have been expired by the scheduled installation date.
What will you do?

Correct

That's right! Only tools with valid calibration can be used.

Continue

Knowledge Check 3

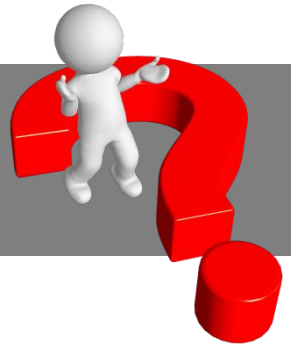
You are preparing your tool box for an upcoming i2000SR installation next week and you discover that the calibration date of your Multimeter will have been expired by the scheduled installation date.
What will you do?

Incorrect

You did not select the correct response. Only tools with valid calibration can be used.

Continue

Knowledge Check



Question 4

Select correct response

For the Net Promoter Score we are classifying customer in 3 different categories: Promoters, Passives and Detractors.

What is a Detractor?

- A potential customer who had never before placed an order with Abbott.
- A customer who is disappointed by Abbott and is likely to speak badly about Abbott and Abbott's products.
- A customer who will highly recommend Abbott to his best friend.

Knowledge Check 4

For the Net Promoter Score we are classifying customer in 3 different categories: Promoters, Passives and Detractors. What is a Detractor?

Correct

That's right! A Detractor is disappointed with Abbott or Abbott's products, and is likely to speak badly about us.

Continue

Knowledge Check 4

For the Net Promoter Score we are classifying customer in 3 different categories: Promoters, Passives and Detractors. What is a Detractor?

Incorrect

You did not select the correct response. A Detractor is disappointed with Abbott or Abbott's products, and is likely to speak badly about us.

Continue

Abbott

End of Unit 5

Minimum Essential Quality Elements
Unit 5: Knowledge Check

This concludes Unit 5, "Knowledge Check"

Click "END" to complete this course.

END

Congratulations!
You have completed this course on Minimum Essential Quality Elements for Distributor Employees with Service Activities.

Complete and sign the training record provided to you and return it to your Abbott contact.

If you are managing a department or you are a Supervisor:

- Act as trainer for your respective area and deliver the training to employees requiring the course material.
- Collect the signature of all employees who attended your training and keep the training record(s).

-- END OF COURSE --
Press "Esc" key to exit.