



# Data Analysis for Risk-Based Improvement

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# Overview



Time	Activity
9:00 – 9:15 am	Introductions
9:15-10:15 am	Learning Objectives Data Collection Basics Break into groups Exercise 1: Data Collection Systems: The good, the bad, and the ugly Exercise 1: Review Data Analysis Basics
10:15-10:30 am	Break (return to groups)
10:30-11:00 am	Data Analysis Basics (cont.) Exercise 2: Setting up Big Data for your Organization Exercise 2: Presentations
11:00-12:00 pm	Using Data Analysis for Continual Improvements Using Risk as Inputs in Decision-Making Exercise 3: Evaluating risk based upon data

# Learning Objectives



This seminar is a combination of presentations, participatory exercises, and discussions covering:

- Data analyses and continual improvement basics
- How data analyses interact with your organization's Quality Management System
- Integrating risk-based thinking into making improvements
- Making data work for your organization's improvements

# Data Collection Basics

# Data Collection

- Data = facts about an object (ISO 9001:2015, 3.8.1)
- Gathering of information in a systemic manner.

**I collect, therefore I  
analyze**

# Group Exercise 1: Data Collection Systems: The good, the bad, and the ugly

# Group Exercise 1

- Select a data collection system (could be electronic, paper, computer-based) that **adds value** and is used for **analysis outside of work**.
  - Write down:
    - What system was selected
    - Why it adds value for you (use brief statements) (the good)
    - What can be improved or what concerns you (the bad)
    - If it is good for some users and bad for other users add them to your good list and your bad list then write “ugly” at the end of the statement

# Exercise 1 Review: “The good”

- There are common themes to good data collection systems that are used for analysis. For example:
  - Easy to use
  - Helps predict issues
  - Aligns with what I need (my process)
  - Real-time data available (minimal lagging data) / Allows you to understand your status at any time
  - Well-organized
  - Users can find and interpret information
  - Allows for organization/sorting of data to suit your needs
  - The data is reliable
  - The data stored is secure and well-controlled

# Exercise 1 Review: “The bad”

- Common deficits in data collection systems include:
  - Data not being current
  - Not having the right data set
  - You cannot organize/sort the data the way you need to
  - Cannot export the data/or it is not exportable in a way you can use it
  - Data is hard to find
  - It is difficult to interpret the data
  - Perhaps the fields names are hard to understand or you cannot tell what data set you are viewing
  - There is so much data it is hard to filter what you need
  - Security breaches
  - Compatibility issues (i.e. the system does not work well with your preferred browser or operating system)
  - System is too slow

# Exercise 1 Review: “The ugly”

- There are some common ugliness in collection systems. The following are very common.
  - Speed
  - User friendliness
  - Compatibility
  - Data Availability

# Data Analysis Basics

# Data Analysis History

*Carte Figurative* des pertes successives en hommes de l'Armée Française dans la campagne de Russie 1812-1813.  
 Dessiné par M. MINARD, Inspecteur Général des Ponts et Chaussées en retraite. Paris, le 20 Novembre 1869.

Les nombres d'hommes présents sont représentés par les longueurs des zones colorées à raison d'un millimètre pour dix mille hommes, ils sont de plus écrits en lettres des zones. Le rouge désigne les hommes qui ont été en Russie, le noir ceux qui en sont sortis. — Les renseignements qui ont servi à dresser la carte ont été puisés dans les ouvrages de M. M. Chiers, de Schur, de Fezensac, de Chambray et le journal inédit de Jacob, pharmacien de l'Armée depuis le 28 Octobre. Pour mieux faire juger à l'œil la diminution de l'armée, j'ai supposé que les corps du Prince Némoï et du Maréchal Davoust qui avaient été détachés sur Minsk et Mohilew et qui rejoindront Orcha et Wilkôk, avaient toujours marché avec l'armée.

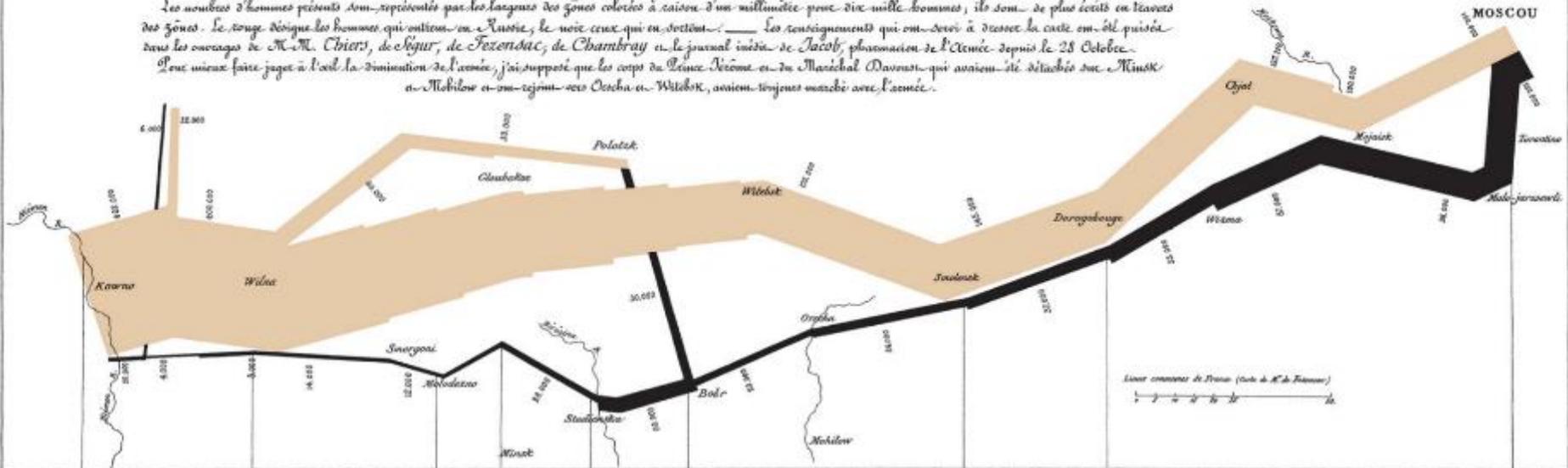
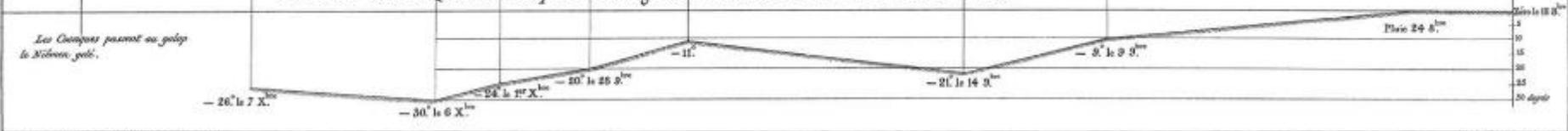


TABLEAU GRAPHIQUE de la température en degrés du thermomètre de Réaumur au dessous de zéro.



Charles Joseph Minard cartographic depiction of losses suffered during the Russian campaign of 1812

# What is data analysis?

“The **process** of extracting, compiling, and modeling raw data for purposes of obtaining constructive information that can be applied to **formulating conclusions, predicting outcomes or supporting decisions**”<sup>1</sup>

# Data Analysis in ISO 9001:2008

## “Analysis of Data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.”

The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1),
- b) conformity to product requirements (see 8.2.4),
- c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) suppliers (see 7.4). (ISO 9001:2008, section 8.4)”

# Data Analysis ISO 9001:2015

## “Analyses and Evaluation

The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

NOTE Methods to analyze data can include statistical techniques. (ISO 9001:2015, 9.1.3)”

## ISO 9001:2015

The results of analysis shall be used to evaluate:

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- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

## ISO 9001:2008

The analysis of data shall provide information relating to

- a) conformity to product requirements (see 8.2.4),
- b) customer satisfaction (see 8.2.1),
- c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and (This one can go in several areas but does not fit nicely in any one category)
- d) suppliers (see 7.4). (ISO 9001:2008, section 8.4)''

Why do you think the ISO 9001 revision is more specific about what analyses will be used for?

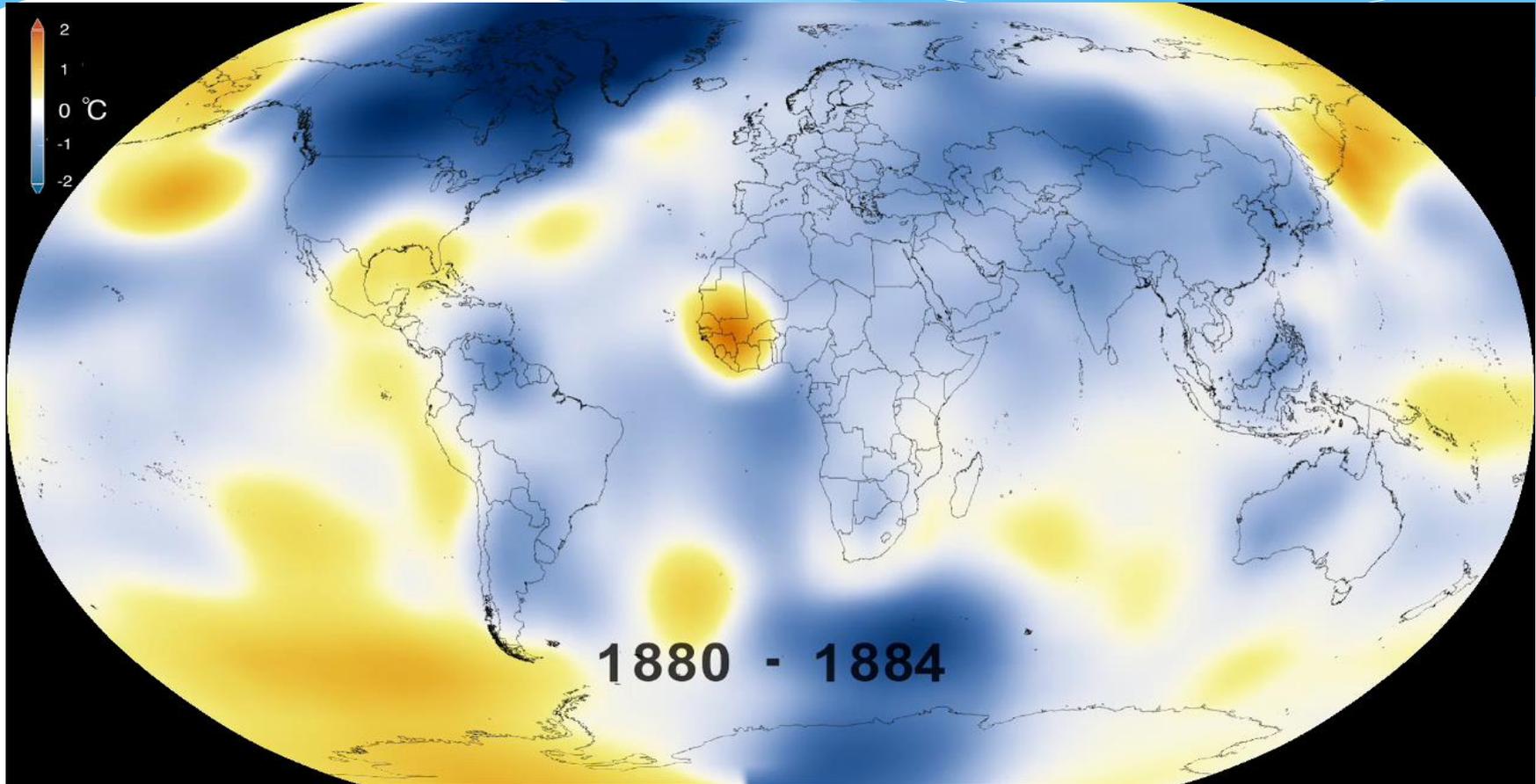
# Type of data analysis

- Examples of data analysis (more than one of these types can be used together):
  - Descriptive/Narrative – Describes data or tells a story
  - Comparative Analysis – compares data set
  - SWOT – Strengths, Weaknesses, Opportunities, and Threats
  - Predictive – Predicts a future outcome by reviewing historic and current states
  - Exploratory – Want to look for connections.
  - Causal/Cause and Effect (a type of Cause and Effect analysis) – What happens to X when you change Y?
  - Visualization <sup>2 & 3</sup>

# Continental U.S. Map of GSFC Supplier in Meta



# Five-Year Global Temperature Anomalies from 1880 to 2015 (Video)<sup>4</sup>



# What is Big Data?

- The term “big data” is used to refer to large data sets that can be analyzed via a system to establish patterns, trends, etc.
  - We use big data for many reasons below are a few:
    - Cost reductions (efficiencies)
    - Time reduction (efficiencies)
    - Stack data
    - Storage<sup>5</sup>
    - Provide information for “risk-based” decisions
    - Allow for organization in a set of data that by itself may be considered overwhelming



ARC Pleides  
Supercomputers

# Break

When you return please get into  
your groups



# Exercise 2: Setting Up Big Data for your Organization



- Assume each group represents a new airplane manufacturing company.
- Each member in your team needs to pick a different role for this exercise:
  - Chief Financial Office Representative (required)
  - Aerospace Engineering (required)
  - Production Manager (oversees technicians) (required)
  - Quality Manager (required)
  - Planner (required)
  - Contract Management/Procurement (required)
  - Receiving Manager (required)
  - Human Resource Manager
  - Safety Manager

# Exercise 2: Setting Up Big Data for your Organization (Cont.)

- Take 10 minutes to discuss with your group and record on your whiteboards:
  - What are some of the supply chain challenges a new company like yours will face?
- Then take 10 minutes to discuss with your groups and record on your whiteboards:
  - How can we use Big Data to help us with these challenges?
    - If we can only implement 3 of these solutions which ones will they be (be prepared to discuss why)

# Data Analysis Recap

- If I collected a lot of data, did I complete my analysis?
  - NO – Having data does not constitute analysis.
- What are two critical elements of data analysis?
  - 1) It is a process
  - 2) It can support decisions
- Can you automate data analysis?
  - YES – In many case the analysis automation leads to outcome automation.
- Does ISO 9001:2015 require data analysis be performed?
  - YES – so did ISO 9001:2008. Requirements have been clarified.
- Do I need big data to understand the effectiveness of my QMS?
  - NO – however, it may be essential in understanding your QMS accurately
- Do I have to select one type of data analysis to use?
  - NO- data analysis needs to connect with its intended audience and can be comprised of several analysis methods

# Using Data Analysis for Continual Improvements



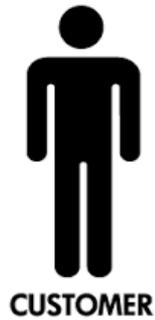
# Continual improvement - what is it? Why do I need it?

- Recurring activity to enhance performance (ISO 9000:2015)
- Improvements are an essential part of your Quality Management System. If you manage a system that does not get better your organization:
  - Will not remain competitive,
  - Will not learn from mistakes,
  - Will not become more efficient over time.

# What drives improvements in your organizations?



**Data Analysis**



**Document Review**



**Kaizen Events**



**Analysis**

# Using risk as inputs into decision making

# What is risk and what is a “risk-based”?



- Risks are defined as:
  - “effect of uncertainty on objectives  
Note 1 to entry: An effect is a deviation from the expected — positive or negative.” (ISO 9000 Quality management systems — Fundamentals and vocabulary and ISO 3100 Risk management — Vocabulary)
- “Risk-based” is a term frequently used in various industries that evaluates collective known risks or risks of not knowing data to make a decision.
- “Decision” = selecting from choices

# ISO 9001:2015 Focus on Risk-Based Thinking



*The concept of risk-based thinking has been implicit in previous editions of this International Standard...*

*The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and replaced by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities...*

*There is no requirement for formal methods for risk management or a documented risk management process...*

*Not all the processes of a quality management system represent the same level of risk...*

# Preventive Action – Where did it go?



“One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or sub-clause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.” (ISO 9001:2015 A.4 Risk-Based Thinking)



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# Evidence-Based Decision Making (2.3.6 ISO 9000:2015)



## “2.3.6.1 Statement

Decisions based on the **analysis** and **evaluation** of data and information are more likely to produce desired results.”

## “2.3.6.2 Rationale

Decision-making can be a complex process and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand **cause and effect relationships and potential unintended consequences**. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making.”

# Evidence-Based Decision Making (2.3.6 9000:2015) (Cont.)

## “2.3.6.3 Key benefits

Some potential key benefits are:

- Improved decision making processes;
- improved assessment of process performance and ability to achieve objectives;
- improved operational effectiveness and efficiency;
- increased ability to review, challenge and change opinions and decisions;
- increased ability to demonstrate the effectiveness of past decisions.

# Evidence-Based Decision Making (2.3.6 9000:2015) (Cont.)

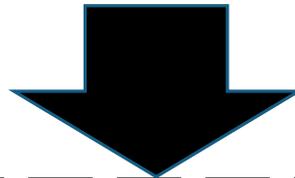
## 2.3.6.4 Possible actions

Possible actions include:

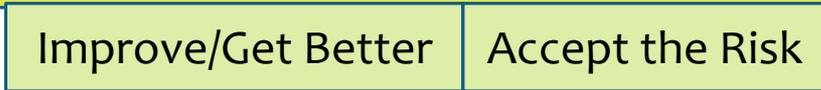
- determine, measure and monitor key indicators to demonstrate the organization's performance;
- make all data needed available to the relevant people;
- ensure that data and information are sufficiently accurate, reliable and secure;
- **analyze and evaluate data and information using suitable methods;**
- **ensure people are competent to analyze and evaluate data as needed;**
- **make decisions and take actions based on evidence, balanced with experience and intuition.**

# How does Risk Based activities fit into Evidence-Based Decision Making?

Inputs



Interpretation/filter all information



# Exercise 3: Evaluating Risk based upon data



Your company is an airplane manufacturer. Based upon the data set that your group receives, perform the following:

- Make a list of your organizations risks.
- From your list, decide upon your top 3 risks.
- What actions would you suggest implementing to address your top 3 risks?

# Wrap-Up

- Effective data collection is necessary for effective data analysis.
- Data analysis is a process and it supports decision making.
- The ISO 9001:2015 revision made requirements more risk-based and dropped many hard requirements, however, the section on Analysis and Evaluation became more prescriptive
- Preventive Actions are now covered in ISO 9001:2015 through use of your risk-based processes in conjunction with continual improvement
- Ensure your analysis connects with your audience
- As data sets grow, the need for Big Data becomes prevalent
- Risk-Based information is an important input to the decision process.

Questions?

# References

- 1) [http://www.investorwords.com/19279/data\\_analysis.html#ixzz4KFqJzxdg](http://www.investorwords.com/19279/data_analysis.html#ixzz4KFqJzxdg)
- 2) <https://datascientistinsights.com/2013/01/29/six-types-of-analyses-every-data-scientist-should-know/>
- 3) <http://www2.uvawise.edu/pww8y/Resources/Methods/TypesAnalysis/00TypesAnalysis.html>
- 4) <https://svs.gsfc.nasa.gov/cgi-bin/details.cgi?aid=4419>
- 5) <https://www.sas.com/resources/asset/Big-Data-in-Big-Companies.pdf>

# Backup Slides

