Statistically Significant Increase

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Topics

- The Concept of Statistical Significance
- Time Series
- Calculating a Trend Line
- Trend Reporting Plan
- Using Excel to Test for Statistical Significance
- Using an ISO 14971:2007 Risk Matrix
- Exercise G1 – Developing the Trend Reporting Plan
- Questions

The Concept of Statistical Significance

Concept

- Data changes over time
- In its most simple form the questions is, “When I see the change is it just noise in the data, or has some more fundamental happened?”
- In more technical terms, we want to distinguish between:
  – Random variability
  – Statistically significant change

Statistically Significant Change

- To answer the previous question, we need a statistical test
- The basic idea forms the hypothesis (the *null hypothesis*) that the observed difference in the data is due to random variation and the underling process has not changed
- An *alternate hypothesis* suggests that the underlying process did change creating the observed difference in the data
- Fischer developed a method to distinguish between the two hypotheses, a test of significance
- He suggested looking at the probability that the change is real using a “rule of thumb” that a probability of one in twenty (0.05) is a convenient cutoff level to reject the null hypothesis (the *significance level*)

An Example

- A production machine is repaired and put back in service. Before the repair, a Critical to Quality (CQT) characteristic had a mean value of 80. Is it still 80 after the repair? The Quality Engineer believes the process variability, $\sigma = 5$, is not affected by the repair. She takes a sample of 50 pieces after the repair and determines the sample mean is 78.8.

- The null and alternative hypotheses

$$H_0: \mu = 80$$
$$H_1: \mu \neq 80$$

- The significance level $\alpha = 0.05$ or 5%

- Is the machine's output after the repair is the same as before, or did the machine change?

Time Series

Time Series

- The PMS data typically does not look like the data in our example. Instead, it comes over time. The data is often reviewed in time order, perhaps monthly.
- This forms a time series.
- In the most common case, we receive complaints, group them by month received, and plot them on a graph in month order. This plot is a time series.

What It Is

- 4.13.1 What it is
- Time series analysis is a family of methods for studying observations made sequentially over time. It includes analytical techniques such as:
  - Statistical significance tests on the parameters that describe the time series
  - Finding "lag" patterns by statistically looking at how each observation is correlated with the observation immediately before it, and repeating this for each successive lagged period
  - Finding patterns that are cyclical or seasonal
  - Using statistical tools to predict future observations or to understand which causal factors have contributed most to variations in the time series

Adapted from ISO 10017:2003,4.13.1

Run Charts

- A run chart (trend chart) is a plot of a characteristic of interest over a period of time to observe its behavior
- The run chart is a line graph with time on the x-axis and the observations on the y-axis
- We consider time series with discrete-time; the observations are a discrete set
  - This contrast with continuous-time where observations are taken continuously over a time interval

Analysis

- Plot the data in time series order
- Look for any of the following:
  - A trend
  - A cyclic component
  - Any sharp changes
  - Any outliers

Examine the Data

- Examine the plotted data
- If there are any discontinuities, consider examining the data in segments
- If there are any outliers, try to understand why
  - Was the observation recorded correctly?

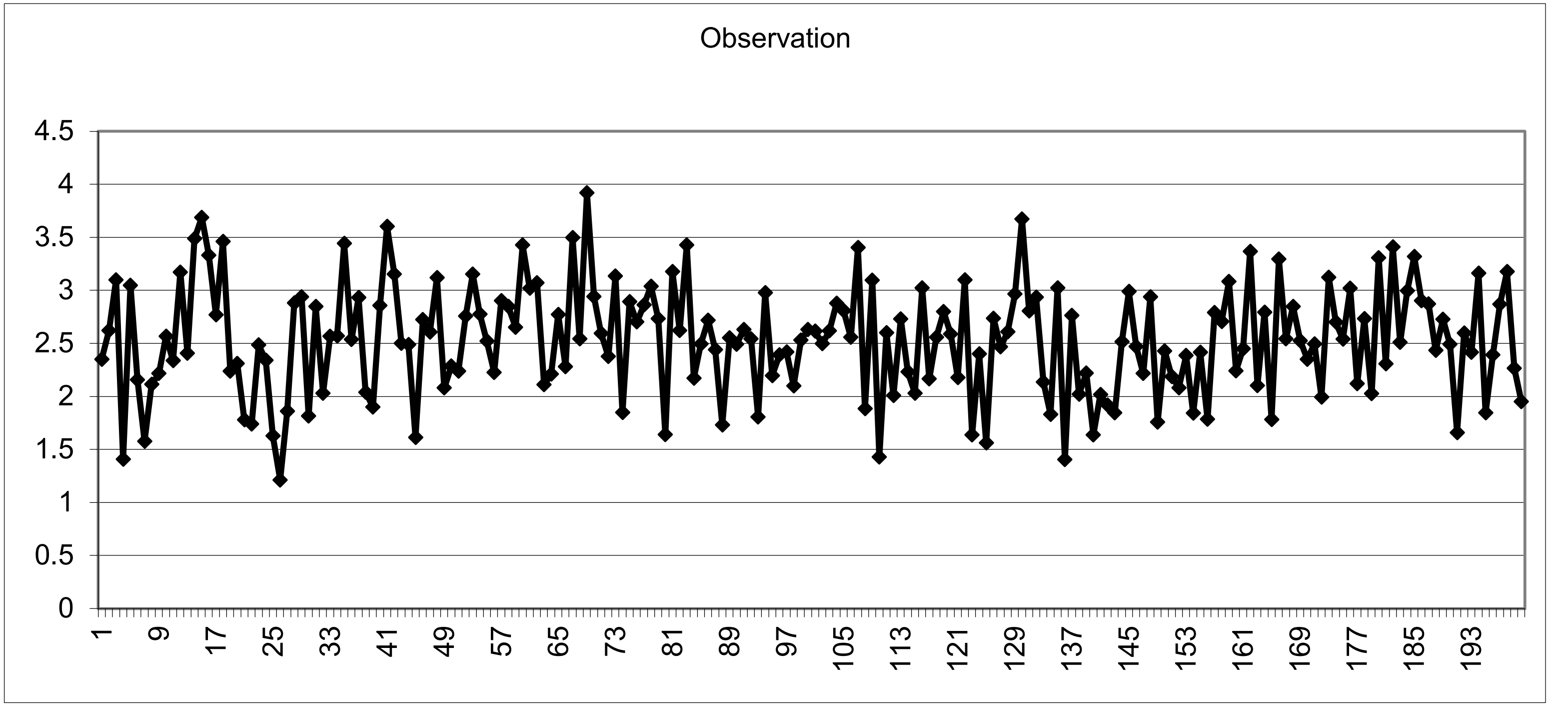
Decomposition

- In the classic decomposition, each observation at time *t*, is written:

$$x_t = m_t + c_t + y_t$$

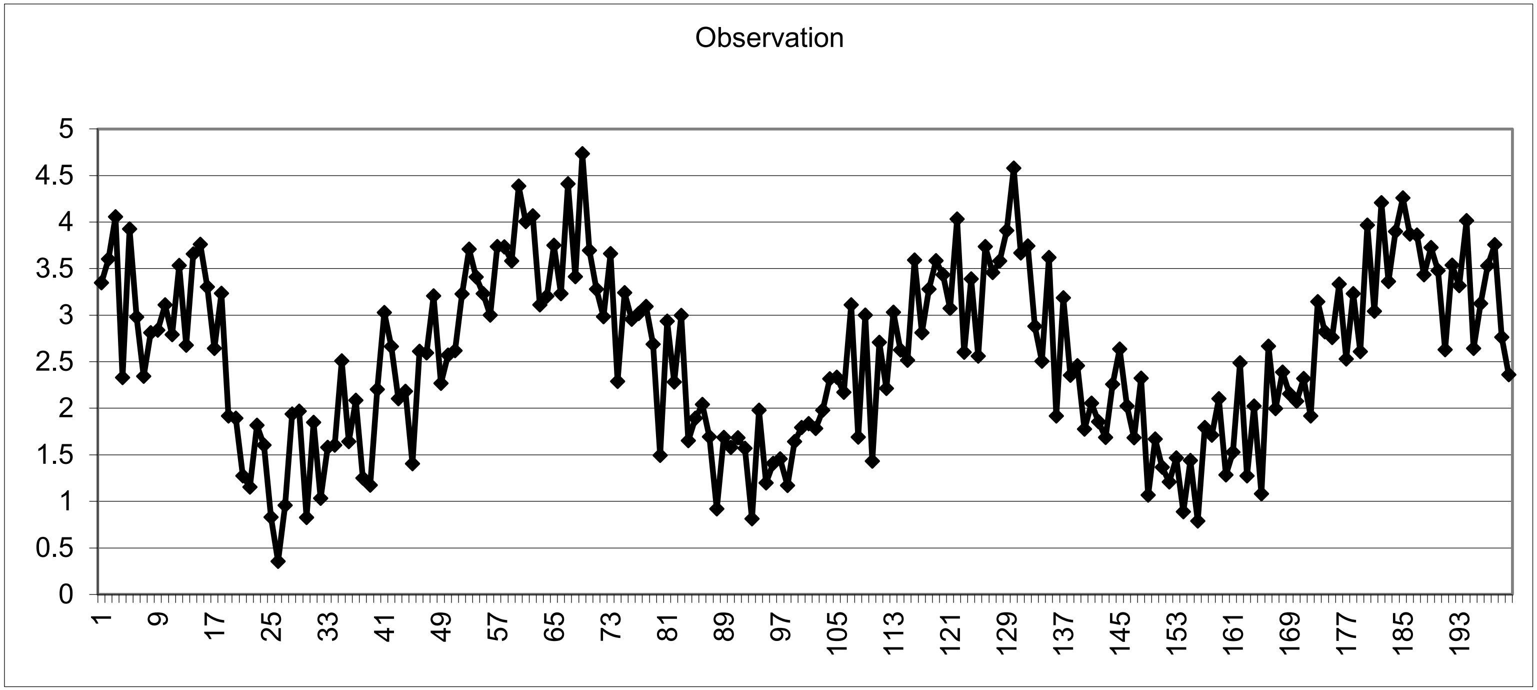
- Where
  - m_t is the trend component
  - c_t is the cyclic component with period *d*
  - y_t is the random noise component

Example #1



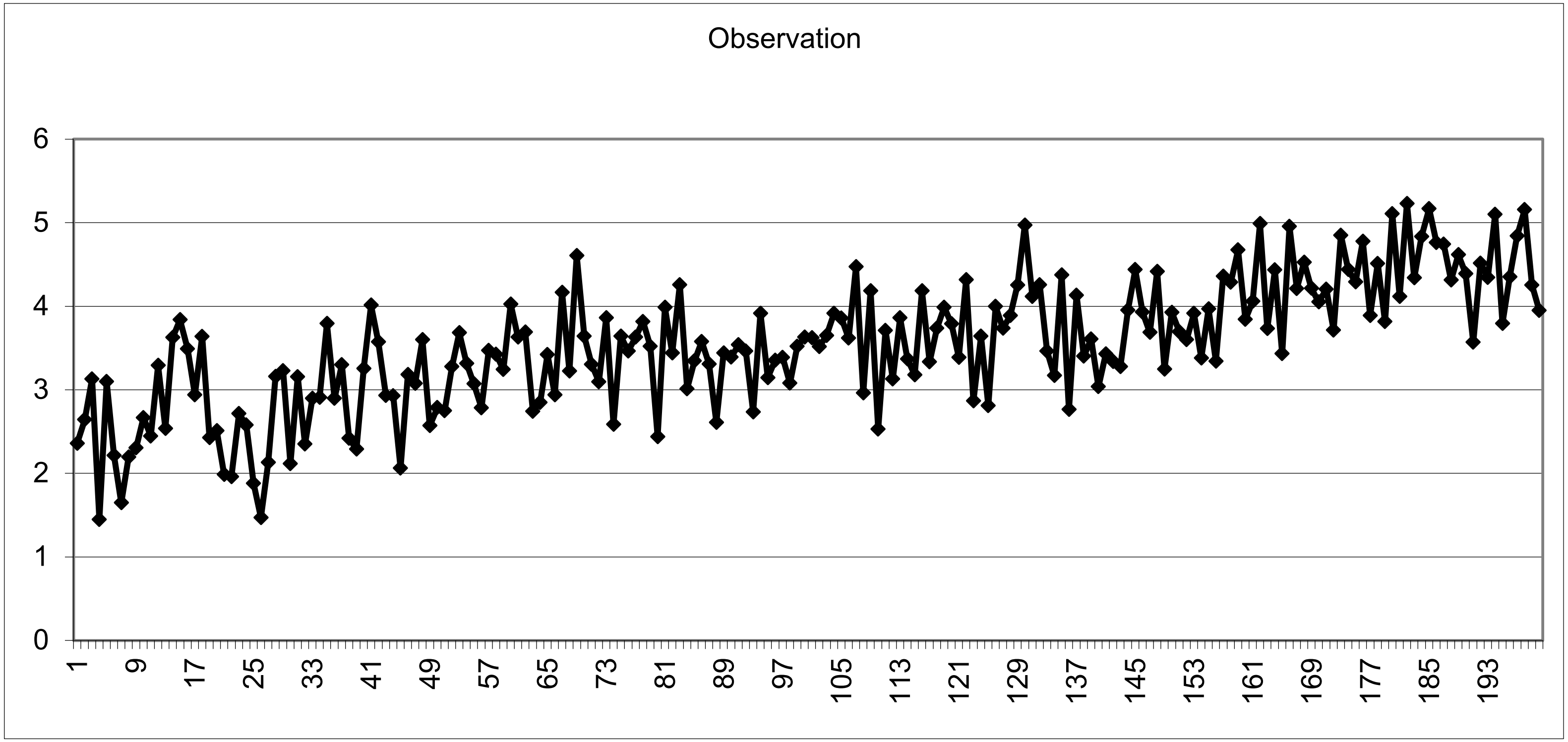
This data set has a constant trend component and no cyclic component

Example #2



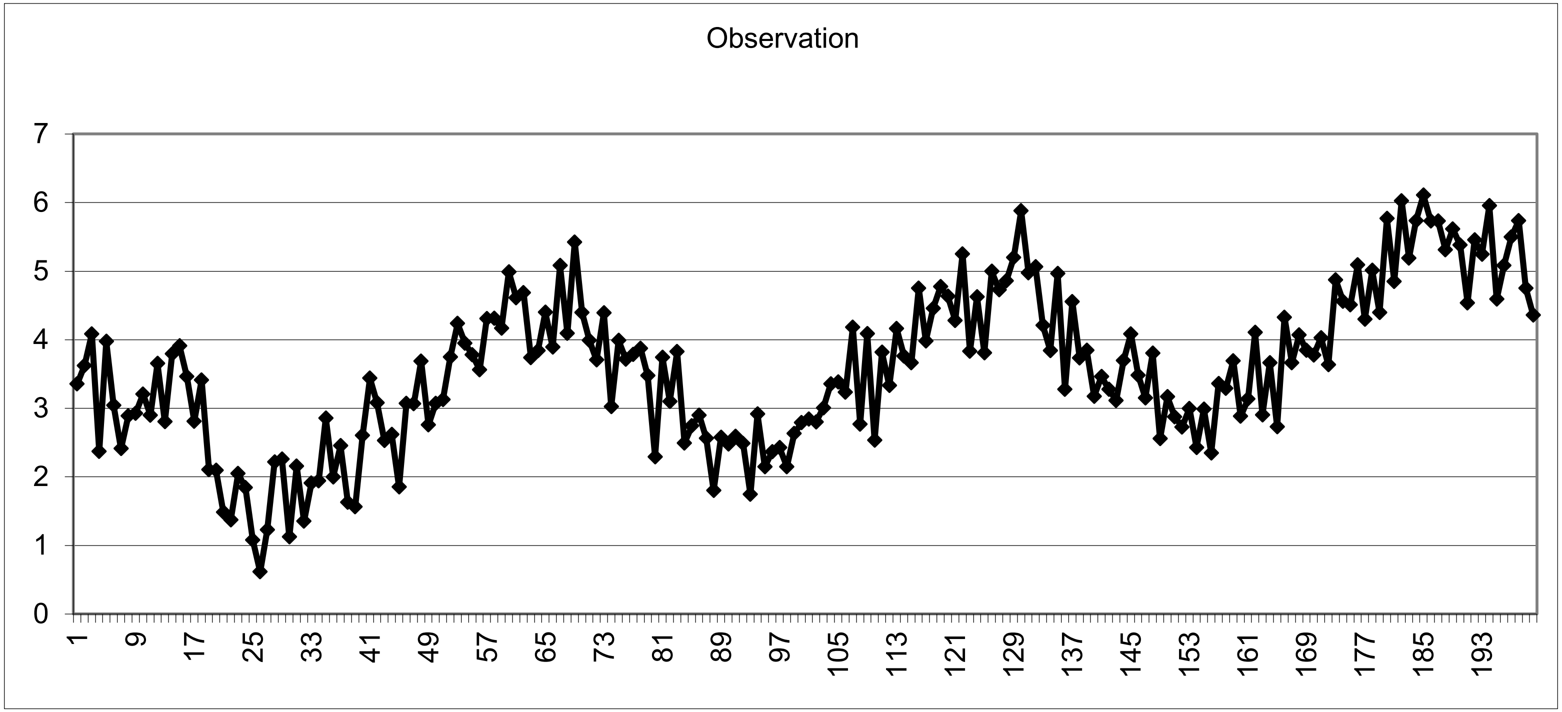
This data set has a constant trend component and an obvious cyclic component

Example #3



This data set has an increasing trend component, but no cyclic component

Example #4



This data set has an increasing trend component and an obvious cyclic component

Calculating a Trend Line

Determining the Components

- One of the questions is to determine the components of a data set

- While there are detailed statistical techniques beyond the scope of this presentation, MS Excel has some valuable tools

Trend

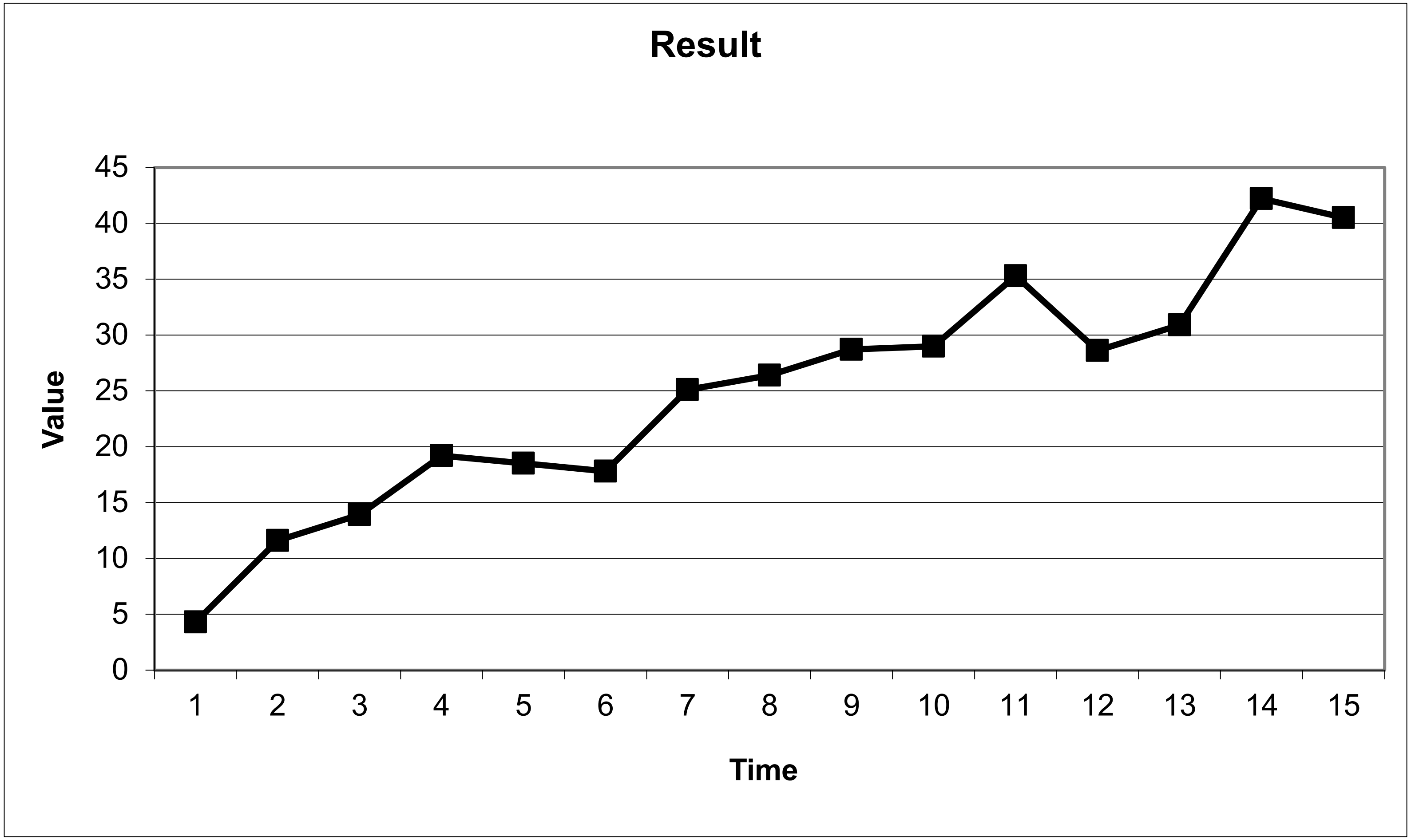
- Usually, trend is determined as a linear regression model.
- This means fitting a straight line to the data and determining the equation of the straight line.
- The straight line fit uses the least-squares method.
  - Find a line and measure the vertical distance from the line to each point in the run chart.
  - Sum the square of each distance
  - The line with smallest value of the sum, <u>the least square distance</u>, is the line that best fits the data

Drawing the Trend Line

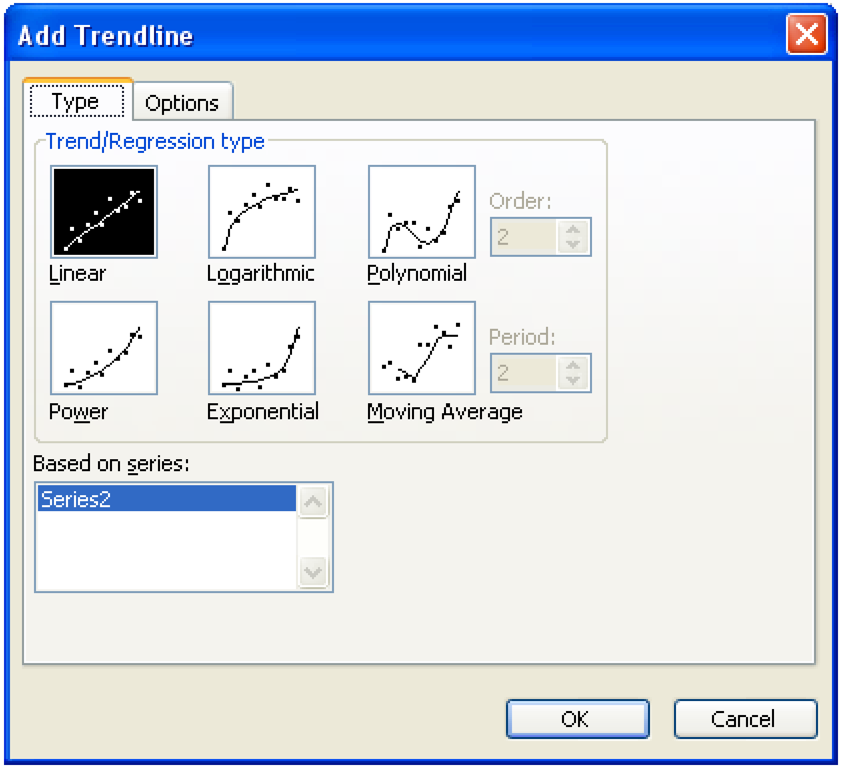
- Excel can put the linear regression line on the graph, and offers the option to display the line's equation and the value of R^2

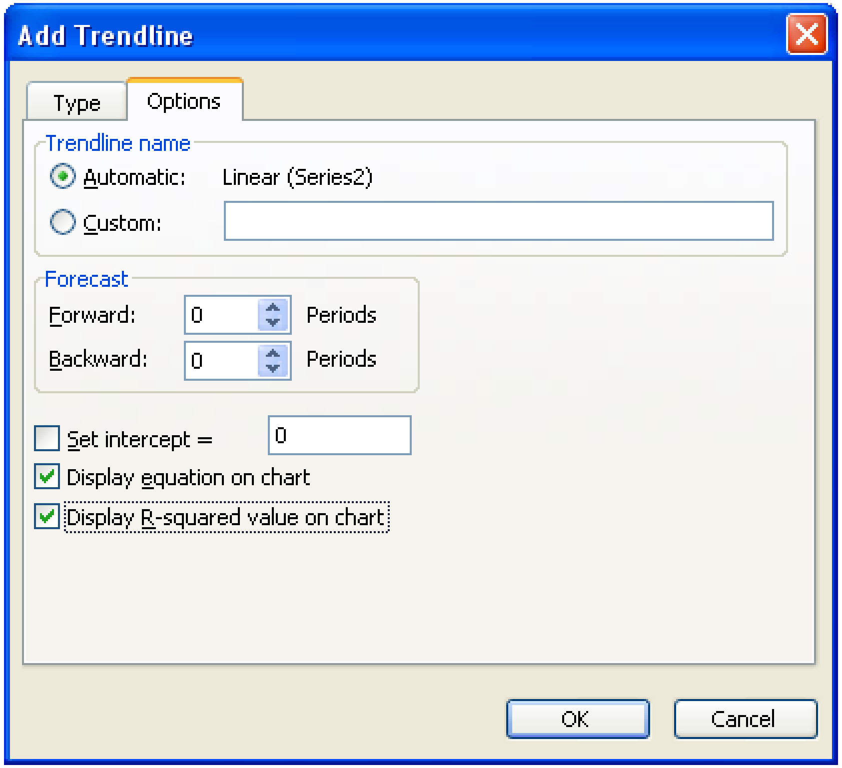
- Plot the run chart and then use the Add Trendline dialog box to add the line and equations to the chart

Run Chart

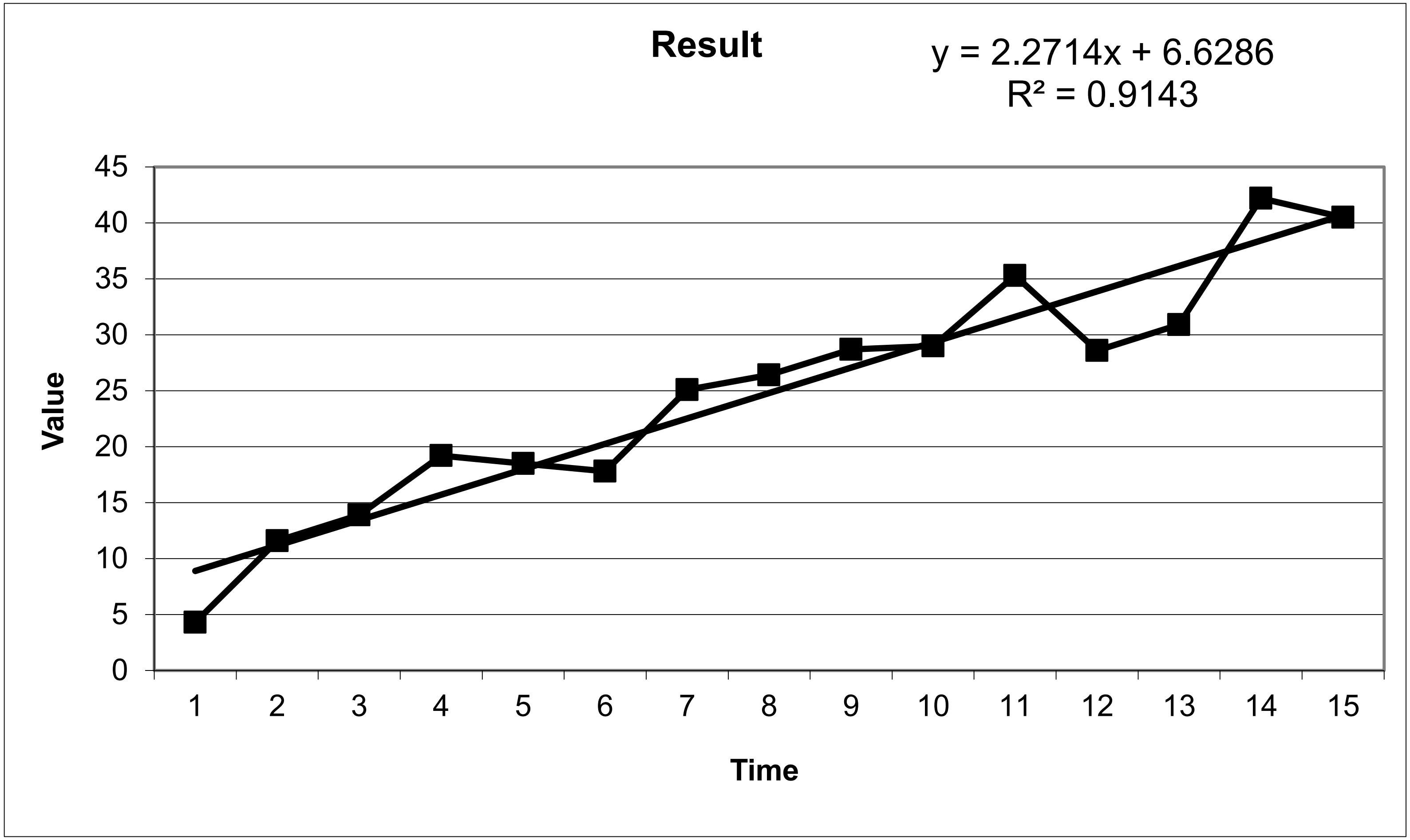

Result
Value
45
40
35
30
25
20
15
10
5
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
Time

Add Trendline





Run Chart + Trendline



Interpreting the Trendline

- A straight line has the equation

$$y = \beta_1 x + \beta_0$$

  - β_1 is the slope of the line
  - β_0 is where the line crosses the y-axis, the intercept

- The R^2 value is a measure of how well the linear trend line explains the data.
  - Numbers closer to ±1 provide “more” explanation

Formulas in Excel

- While the information on the graph is very useful, sometimes you need it in a worksheet cell for use in other computations.

- The functions are:
  - SLOPE(known_y's, known_x's) – Returns the slope of the linear regression line through the data points. The slope is the vertical distance divided by the horizontal distance between any two points on the line, which is the rate of change along the regression line

  - INTERCEPT(known_y's, known_x's) – Returns the point at which a line will intersect the y-axis by using existing x-values and y-values

  - RSQ(known_y's, known_x's) – Returns the square of the Pearson product moment correlation coefficient. The r-squared value can be interpreted as the proportion of the variance in y attributable to the variance in x

Trend Reporting Plan

Characteristics

- Article 88(1)
- Establish the significant increase in comparison to the foreseeable frequency or severity of such incidents
- Establish “the baseline” during a specific period
- Specify how to manage the incidents
- Specify the methodology used for determining any statistically significant increase in the frequency or severity of such incidents
- Specify the observation period

Using Excel to Test for Statistical Significance

Is There a Trend?

- One common question asks if the data plotted on the run chart shows a trend.
  - There are empirical rules such as seven points in a row that are increasing or decreasing
- Another method uses statistical techniques to determine if the slope is statistically significant
  - If there were no trend, the slope would be zero
  - If the slope were not zero it might be just random variability or because there is a trend

Hypothesis Test

- The population relations use the equation

$$y = \beta_1 x + \beta_0$$

- When look at the samples, we use

$$y = b_1 x + b_0$$

- Phrased as a hypothesis test, the null hypothesis is that there is no trend, *i.e.,* the slope is zero:

$$H_0: \beta_1 = 0$$
$$H1: \beta_1 \neq 0$$

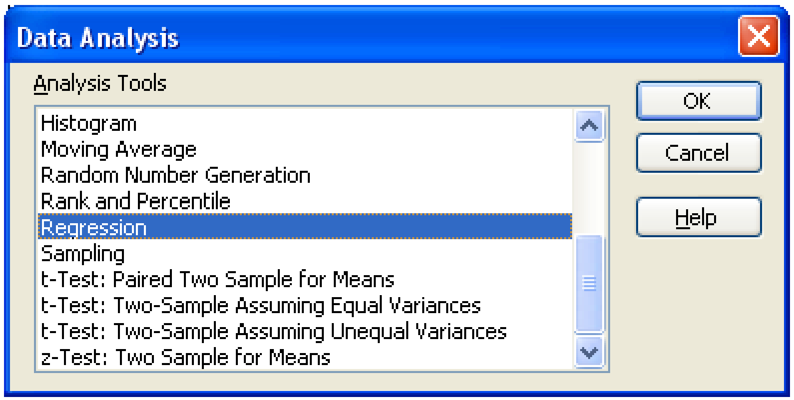
Hypothesis Test

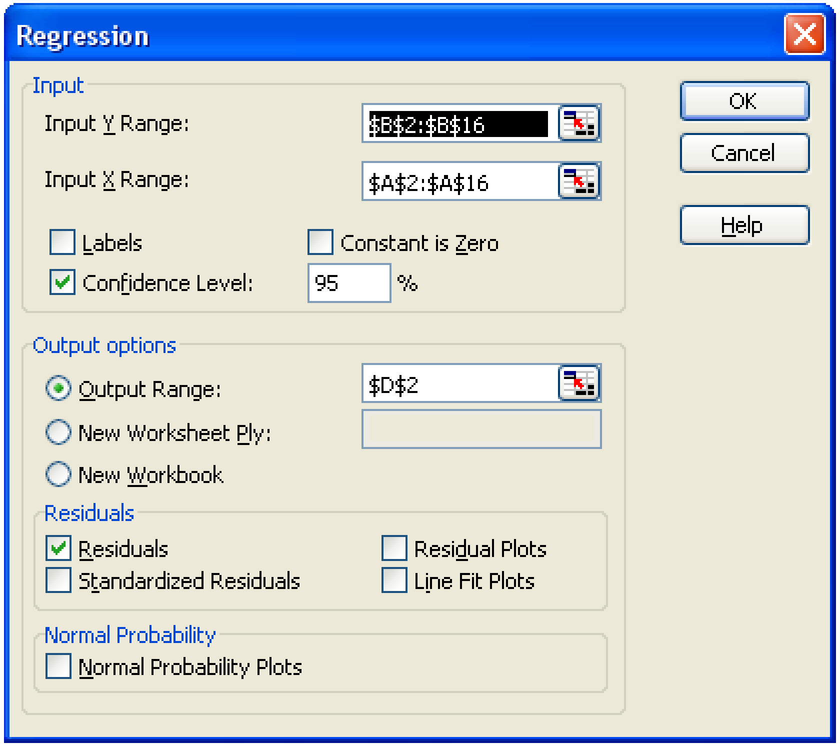
- Fortunately, Excel can solve this problem easily

- First, use the Analysis Tool Pack
  - If is not available, you have to load it

  - Enter Analysis Tool Pack into Help and follow the directions
    - Each version of Excel is slightly different

Analysis Tool Pack





The Output

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.956201799
R Square	0.914321881
Adjusted R Square	0.907731256
Standard Error	3.22694698
Observations	15

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	1444.628571	1444.628571	138.7306881	2.61248E-08
Residual	13	135.3714286	10.41318681		
Total	14	1580			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	6.628571429	1.753387989	3.780436201	0.002290939	2.840606974	10.41653588	2.840606974	10.41653588
X Variable 1	2.271428571	0.192846968	11.77839921	2.61248E-08	1.854808027	2.688049116	1.854808027	2.688049116

Slope

Confidence Intervals

The Result

- We get back a lot of data, but only some of this is of interest in answering the question.

- In our example for the run chart, the slope is 2.271

- The hypothesis test uses the *t*-test
  - The value of the *t*-statistic is 11.778
  - The probability of getting this value is 2.612E-08
  - With these values, we can reject the Null Hypothesis

- In addition, we get the upper and lower confidence intervals on the slope
  - Upper 95% is 2.688
  - Lower 95% is 1.855
  - Because the confidence interval does not include 0.000 we have further evidence the slope is not zero

- We conclude that there is a linear trend

Using an ISO 14971:2007 Risk Matrix

Risk

- Risk means the combination of the severity of the harm and its frequency of occurrence.

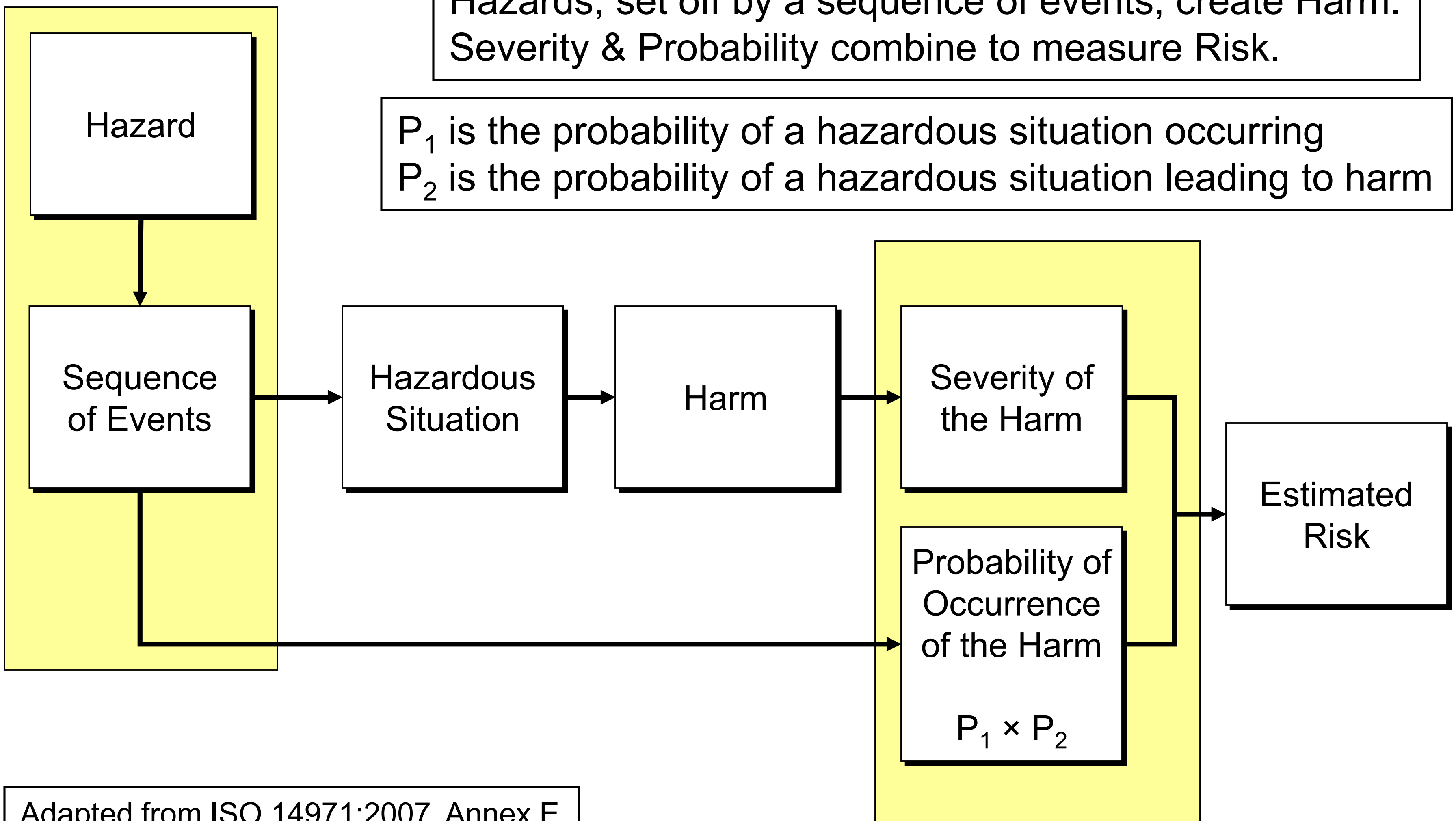
- In ISO 14971:2007 the definition of risk is “combination of the probability of occurrence of harm and the severity of that harm”
  - There are technical reasons why probability is not the right word.

- In Risk Analysis, determine the harm, its severity, and how often it happens.

The Components of Risk

Hazards, set off by a sequence of events, create Harm.
Severity & Probability combine to measure Risk.

P_1 is the probability of a hazardous situation occurring
P_2 is the probability of a hazardous situation leading to harm



Adapted from ISO 14971:2007, Annex E

Severity

- Most harms have severity levels. A common example is a burn.
- First-degree burns affect the outer layer of the skin only. The burn site is red, painful, dry, and without blisters.
- Second-degree burns involve the outer layer of the skin and part of the next layer. The burn site appears red, blistered, and may be swollen and painful.
- Third-degree burns destroy layers of the skin. The burn site may appear white or charred.

Severity Table

Severity Levels	
Term	Description
Catastrophic	Results in death
Critical	Results in permanent impairment to life-threatening injury
Serious	Results in injury or impairment requiring medical intervention
Minor	Results in injury or impairment not requiring medical intervention
Negligible	Inconvenience or temporary discomfort

Based on Table D.3 – Example of five qualitative severity levels

The manufacturer chooses the severity levels based on clearly defined conditions of use.

Frequency

- Frequency is a measure of how often the harm occurs with the specified severity.

- Frequency of occurrence is a rate, meaning it has a numerator and a denominator.
  - Consider a single use device that causes a particular harm/severity 3 times in every 1,000 uses.
  - This is the rate of occurrence and may be expressed in a variety of ways:
    - 3/1000
    - 0.003 3.0×10^{-3}
    - 0.3% 3,000 ppm

Frequency Scales

- The definitions for frequency can be different for different product families. For example, a manufacturer can choose to use one set of definitions for X-ray machines, but can have a different set of definitions for sterile disposable dressings.
- Different measures of frequency may be appropriate, depending upon the application.
- Frequency scales can include “frequency of harm per use”, “frequency of harm per device”, “frequency of harm per hour of use”, *etc*.
- Specify the frequency scale in the Risk Management Plan and ensure all team members understand it.

Frequency Table

Frequency Levels	
Term	Description
Frequent	Happens often
Probable	Likely to happen
Occasional	Can happen, but not likely
Remote	Unlikely to happen
Improbable	Highly unlikely to happen

Frequency Levels	
Term	Frequency Range
Frequent	$\geq 10^{-3}$
Probable	$< 10^{-3}$ and $\geq 10^{-4}$
Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
Remote	$< 10^{-5}$ and $\geq 10^{-6}$
Improbable	$< 10^{-6}$

Residual Risk

- After implementation of the risk control measures, estimate the residual risk and apply the acceptability criteria.
- When the device is released for production, then the residual risk from each harm falls into one (and only one) cell on the risk matrix.
- Observe the information from PMS.
  - Set an observation time, say a moving six month window.
  - The frequency of occurrence (remember this is a rate) should be in the same row as the estimated residual risk
  - The severity should be in the same column as the estimated residual risk
  - If the observed frequency moves to a higher row, then generate a signal
  - If any observed severity is to the right of the estimated residual risk, generate a signal

An Example

Signal
Frequency increased

		Severity Levels				
		Negligible	Minor	Serious	Critical	Catastrophic
Frequency	Frequent	R2	R2	R3	R3	R3
	Probable	R2	R2	R2	R2	R3
	Occasional	R2	R2	R2	R2	R3
	Remote	R1	R1	R2	R2	R3
	Improbable	R1	R1	[illegible]	[illegible]	R3

R1 Acceptable – Negligible
R2 Acceptable with Risk Minimization
R3 Unacceptable

Estimated residual risk
(Remote, Serious)

Signal
1 or more critical severity

QUESTIONS