

# Case Study: A Mock-QSIT Audit of Ford & Firestone

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## Background

In December the Firestone Company released a report on the tires involved in the recall of 2000. The media reported that over 140 fatalities were attributed to the Ford Explorer vehicle and Firestone Wilderness AT tire combination.

The company stated that a root cause team worked very hard to uncover the problems. They reported that their investigation found several issues. They say the problem was with the process, not the quality of workmanship. While Firestone has publicly released the report, Ford still denies any fault in the matter.

In this article I will discuss some of the known facts – and some of the reported facts in this matter, and look at them from a quality system perspective. It is important to note that none of the facts have been documented as “objective evidence” which normally would be done during an audit. As a case study exercise, a mock-483 is provided to place the findings in a medical device quality system framework.

## The Report

On December 18 Firestone released a report stating the following:

- 1) Too much chemical was used bonding two layers of steel belts. It was actually weakening the bond between the belts and the rubber.
- 2) The design of the treads was too deep on the edges of the tires - where the most heat occurs on the tire. The thin rubber at this location allowed cracking to occur.
- 3) Weight was added to the left rear of vehicle – the most common location of tire separation. (Allegedly - without telling firestone)
- 4) Customers were told by Ford to deflate the tires from 35 to 26 pounds (some reports say it was to deal with a rollover problem – others say it was to address customers wanting a smoother ride). Note: Deflation puts more heat and pressure on those weak corners described above.

A mock-483 is provided. Using the QSIT subsystems the breakdown of subsystem observations is as follows:

Management Controls	3 observations
Design Controls	4 observations
Corrective & Preventive Actions (CAPA)	7 observations
Production & Process Controls	2 observations

It is interesting to note that only two observations were made under production & process control (PPC), and one was for training (a management control requirement). As we all learned during the advent of design controls, good PPC can ensure that you manufacture millions of a product with the same inherent design weakness.

A chart showing the QSIT and the Quality System correlation is provided. I have found this type of chart is a useful tool when reviewing audit findings.

<b>Observation Number</b>	<b>QSIT Subsystem</b>	<b>QSIT Item Number in the Subsystem</b>	<b>Quality System Section</b>	<b>Description of Finding</b>
<b>1</b>	<b>Mgt.</b>	<b>Mgt 7</b>	<b>820.20</b>	<b>Adequate Quality System not Implemented</b>
<b>2</b>	<b>Mgt.</b>	<b>Mgt 5</b>	<b>820.20(c)</b>	<b>Management Review not adequate</b>
<b>3</b>	<b>Mgt.</b>	<b>Mgt 6</b>	<b>820.22</b>	<b>Audits not adequate</b>
<b>4</b>	<b>Design</b>	<b>Design 11</b>	<b>820.30(g)</b>	<b>Risk Analysis not adequate for design change</b>
<b>5</b>	<b>Design</b>	<b>Design 6</b>	<b>820.30(g)</b>	<b>Acceptance Criteria for design change not adequate</b>
<b>6</b>	<b>Design</b>	<b>Design 8</b>	<b>820.30(g)</b>	<b>Validation of Design for design change not adequate</b>
<b>7</b>	<b>Design</b>	<b>Design 13</b>	<b>820.30(i)</b>	<b>Design changes – general procedures and policies</b>
<b>8</b>	<b>PPC</b>	<b>PPC 6</b>	<b>820.25(a)</b>	<b>Training not adequate</b>
<b>9</b>	<b>PPC</b>	<b>PPC 2</b>	<b>820.70(a)</b>	<b>Process not controlled</b>
<b>10</b>	<b>CAPA</b>	<b>CAPA 2</b>	<b>820.100(a)(1)</b>	<b>Failure to input CAPA data</b>
<b>11</b>	<b>CAPA</b>	<b>CAPA 5</b>	<b>820.100(a)(1)</b>	<b>Failure to use appropriate statistical methodology when taking action on CAPA data</b>
<b>12</b>	<b>CAPA</b>	<b>CAPA 6</b>	<b>820.100(a)(2)</b>	<b>Root cause analysis not performed soon enough</b>
<b>13</b>	<b>CAPA</b>	<b>CAPA 7</b>	<b>820.100(a)(3)</b>	<b>Correction (the recall) was implemented before root cause was completed</b>
<b>14</b>	<b>CAPA</b>	<b>CAPA 8</b>	<b>820.100(a)(4)</b>	<b>Identification of actions needed was not performed until after correction (recall) was taken</b>
<b>15</b>	<b>CAPA</b>	<b>CAPA 10</b>	<b>820.100(a)(6)</b>	<b>Crucial quality problem data was not disseminated to people who needed to act on the data</b>
<b>16</b>	<b>CAPA</b>	<b>CAPA 10</b>	<b>820.100(a)(7)</b>	<b>Crucial quality problem data was not submitted for management review.</b>

Using traditional FDA 483 language, the sixteen observations are provided below.

**Important Note: Not much objective evidence, aside from media reports was obtained. Thus the validity of some observations is questionable. Using data available from the media, a mock-483 was prepared. This is a learning tool which you may find interesting.**

### **Management Controls**

#### **1. 820.20 Quality System**

Management with executive responsibility did not ensure an adequate and effective quality system was established and maintained. Management controls, design controls, production and process controls and corrective and preventive actions were not adequate.

#### **2. 820.20(c) - Management review**

Management reviews do not ensure that the quality system satisfies the requirements of the regulation. Specifically, according to Newsweek, reports of tire separation and accidents began as early as 1996. Fatalities were not acted upon by top management for several years, when a recall was announced. This indicates that the data was either not fed into management review, or was fed but not acted on.

#### **3. 820.22 - Quality audits**

Quality audits did not verify that the quality system is effective in fulfilling the firm's quality system objectives. Specifically, the audits should have found the weaknesses in the Design, Production & Process Control and CAPA program described below. In addition, Ford, according to TV reports, reportedly did not audit Firestone after placing them on a preferred vendor list.

### **Design Controls**

#### **4. 820.30(g) - Risk analysis**

Risk analysis was either not done or was inadequate. Specifically, risk analysis of the modification to decrease tire pressure did not adequately analyze the effect of the lower pressure on the tires and the vehicle under use conditions (a critical component). Newsweek also reported Ford gave improper tire specifications to its tire suppliers.

#### **5. 820.30(g) - Design validation acceptance criteria**

Acceptance criteria were not adequate, prior to the performance of validation activities. It was reported on TV that Ford tested the vehicles for rollover. It appears that testing (on the change in tire air pressure) used too small a sample and vehicles were not loaded up adequately simulate conditions and to verify the effect of the change on the tires and vehicle.

#### **6. 820.30(g) - Design validation per user needs and intended use**

Design validation did not ensure that devices conform to defined user/patient needs and intended uses. Specifically, the change in weight to the rear of vehicle, alleged by Firestone on TV reports, and the change (decrease) in tire air pressure resulted in major tire separations, rollovers and fatalities.

**7. 820.30(i) - Design changes**

Procedures for design changes before their implementation are not adequate. Specifically, based on the December 18, 2000 Firestone report, the change in tread depth (at the edge of the Wilderness AT tires), the change adding weight to the rear of vehicle and the change in tire air pressure (decrease) resulted in major tire separations, rollovers and fatalities. The changes should have been discussed with Firestone and adequate testing should have been done under various conditions before implementation.

**Production & Process Controls**

**8. 820.25(a) - Personnel education, background, training, & experience**

Employees do not have the necessary training to perform their jobs. Specifically, employees in Decatur, according to TV reports, were using a different process to bond the steel belts than employees in other plants making the same tires. It was reported on TV that workers used during the strike were not adequately trained.

**9. 820.70(a) - Production processes**

Production processes were not controlled to ensure that the product conforms to its specifications. Specifically, too much chemical used to bond the two layers of steel belts was used at the Decatur plant (as opposed to the other plants) according to the root cause analysis reported on TV.

**Corrective and Preventive Actions (CAPA)**

**10. 820.100(a)(1) - CAPA analysis of data sources**

Not all sources of quality data are analyzed to identify existing and potential causes of nonconforming product and other quality problems. Specifically:

**A.** Firestone did not include injury claims in quality assessment because the frequency was so low compared to the number of tires made (according to newspaper articles). In addition lawsuits were settled with families of fatality victims (according to TV stories). Lawsuits should be mentioned in the procedures as a CAPA data source.

**B.** Reports from the vendor/customer are not shared between Ford & Firestone. According to newspapers Bridgestone/Firestone (BF) had originally said they

did not know about the problem until Ford did an analysis of BF's reports of injury or damage.

**11. 820.100(a)(1) - CAPA procedure for statistical methodology**

Corrective and preventive action procedures addressing the use of appropriate statistical methodology to identify existing and potential causes of nonconforming product or other quality problems were not adequate. Specifically, no justification was provided for waiting three years (according to Newsweek) and over 100 rollover fatalities before initiating action.

**12. 820.100(a)(2) - CAPA investigation**

Indicators of nonconformities are not investigated to determine the cause of the nonconformity. Specifically, root cause was not determined before implementation of correction (the August 2000 recall). Root cause evaluation was not completed until December 2000 after at least 140 fatalities (according to TV reports) were documented due to vehicle rollover after tire separation.

**13. 820.100(a)(3) - CAPA identification of actions needed to correct and prevent nonconformities, problems – and timeliness of action.**

A. The actions needed to correct and prevent the recurrence of nonconforming product and other quality problems were not identified at the time of the recall. Specifically, the correction taken (the recall) involved replacement with tires, which reportedly may have the same design and manufacturing characteristics as the recalled tires.

B. In addition, between Jan 19, 2000 and August 9, 2000 at least 16 people reportedly died in rollover accidents. Management knew of the problem on Jan 19, 2000 according to newspaper articles. No corrective action was initiated for almost seven months resulting in 16 new deaths. (Generally the last observation falls under "timeliness" of CAPA activities – QSIT CAPA #4)

**14. 820.100(a)(4) - CAPA verification/validation of corrective/preventive action**

Corrective and preventive actions have not been verified or validated to ensure that the action is effective and does not adversely affect the finished device. Specifically, Root cause analysis was not completed until four months after the recall. Thus verification or validation of the adequacy of the correction (the recall) was not done.

**15. 820.100(a)(6) - CAPA dissemination of problem**

Information related to quality problems or nonconforming product was not disseminated to those directly responsible for assuring the quality of the product and prevention of the quality problem. Specifically, information was not communicated between Ford &

Firestone, and investigations were not initiated within a reasonable time. Ford CEO reportedly stated at a congressional hearing that they had to ask Firestone five times to turn over quality problem (claims) data.

**16. 820.100(a)(7) - Management review of CAPA**

Information on identified quality problems and corrective actions has not been submitted for review by management. Specifically, the CEO of Ford was (claimed) unaware of the fatalities and tire separation problem for several years after the problems were reported.

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