

Standard Operating Procedures

What are SOPs?

- Standard = Routine
- Operating = Working
- Procedures = Methods
- Serves as Regulatory "Memory"
- Serves as Corporate "Memory"

What does the SOP say!!!!!!

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Standard Operating Procedures

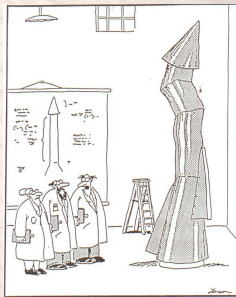
What are SOPs NOT?

- Something to put on a shelf
- Something only used to show regulators or Sponsors
- Something written to avoid deviations
- Something to buy or have a consultant write

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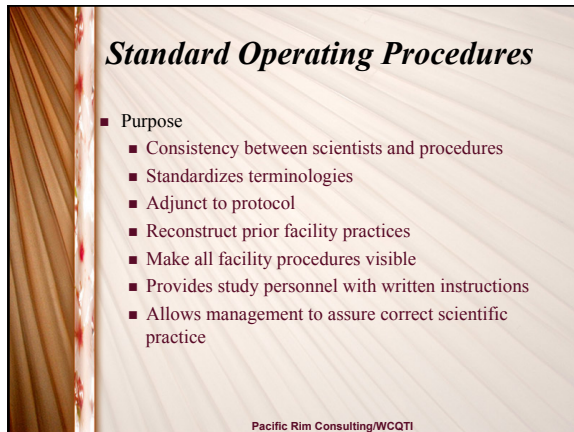
Standard Operating Procedures

- "A testing facility shall have standard operating procedures in writing setting forth study methods **that management is satisfied are adequate to insure the quality and integrity** of the data generated in the course of a study."



"It's time we face reality, my friend. ... We're not exactly rocket scientists."

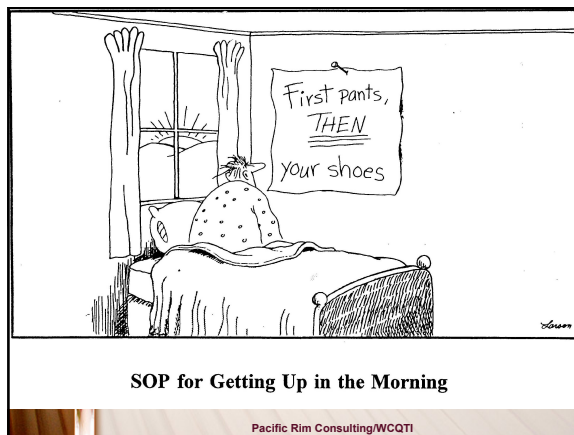
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Standard Operating Procedures

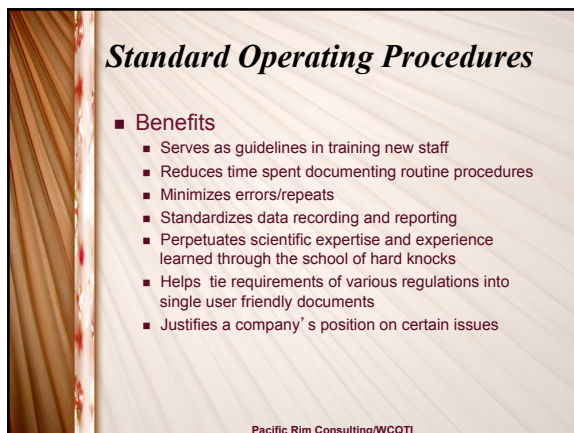
- Purpose
 - Consistency between scientists and procedures
 - Standardizes terminologies
 - Adjunct to protocol
 - Reconstruct prior facility practices
 - Make all facility procedures visible
 - Provides study personnel with written instructions
 - Allows management to assure correct scientific practice

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SOP for Getting Up in the Morning

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Standard Operating Procedures

- Benefits
 - Serves as guidelines in training new staff
 - Reduces time spent documenting routine procedures
 - Minimizes errors/repeats
 - Standardizes data recording and reporting
 - Perpetuates scientific expertise and experience learned through the school of hard knocks
 - Helps tie requirements of various regulations into single user friendly documents
 - Justifies a company's position on certain issues

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Coronary Vasculature
Swine Procedural Record
Interventional Cardiovascular Research Projects
Pg # 99Y

GLP study # _____
Date: ____/____/____ Microchip #: ____*____*____
Sex _____ Weight: _____ lbs. _____ Kg.
Operator: _____ Access: RC LC RFA LFA REJ LEJ RJ LJ
RFV LFV
Protocol: _____ Description: _____
Expected Survival Days: _____

Investigator: Schwartz,
Table on: _____
Table off: _____
Heart rate: _____
Temp: _____
BP: _____
Mean BP: _____
RCA: _____
Vessel size: _____
Location: _____
Injury and/or Rx: _____
TIMI pre: _____
TIMI post: _____
COMMENTS: _____

Right Coronary

Left Coronary

RIGHT CORONARY
1 Distal 12 12 RPL
2 Proximal 12 12 RPL
3 Mid 12 12 RPL
4 Distal 12 12 RPL
5 Proximal 12 12 RPL
6 Mid 12 12 RPL
7 Distal 12 12 RPL
8 Proximal 12 12 RPL
9 Mid 12 12 RPL
10 Distal 12 12 RPL
11 Proximal 12 12 RPL
12 Mid 12 12 RPL
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98 Proximal 12 12 RPL
99 Mid 12 12 RPL
100 Distal 12 12 RPL

LAD:
Vessel size: _____
Location: _____
Injury and/or Rx: _____
TIMI pre: _____
TIMI post: _____
LCX:
Vessel size: _____
Location: _____
Injury and/or Rx: _____
TIMI pre: _____
TIMI post: _____

QUESTIONS?????



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