Responding to 483 Observations: What to Do and How to Do it

Moderator
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Panel
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Susan Rolih, Meridian Bioscience, Inc.
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Background

- During the first quarter 2015, a survey was sent out to the medical device community.
- The subject of the survey was how firms viewed and addressed 483 observations.
- Received 310 responses.

Question

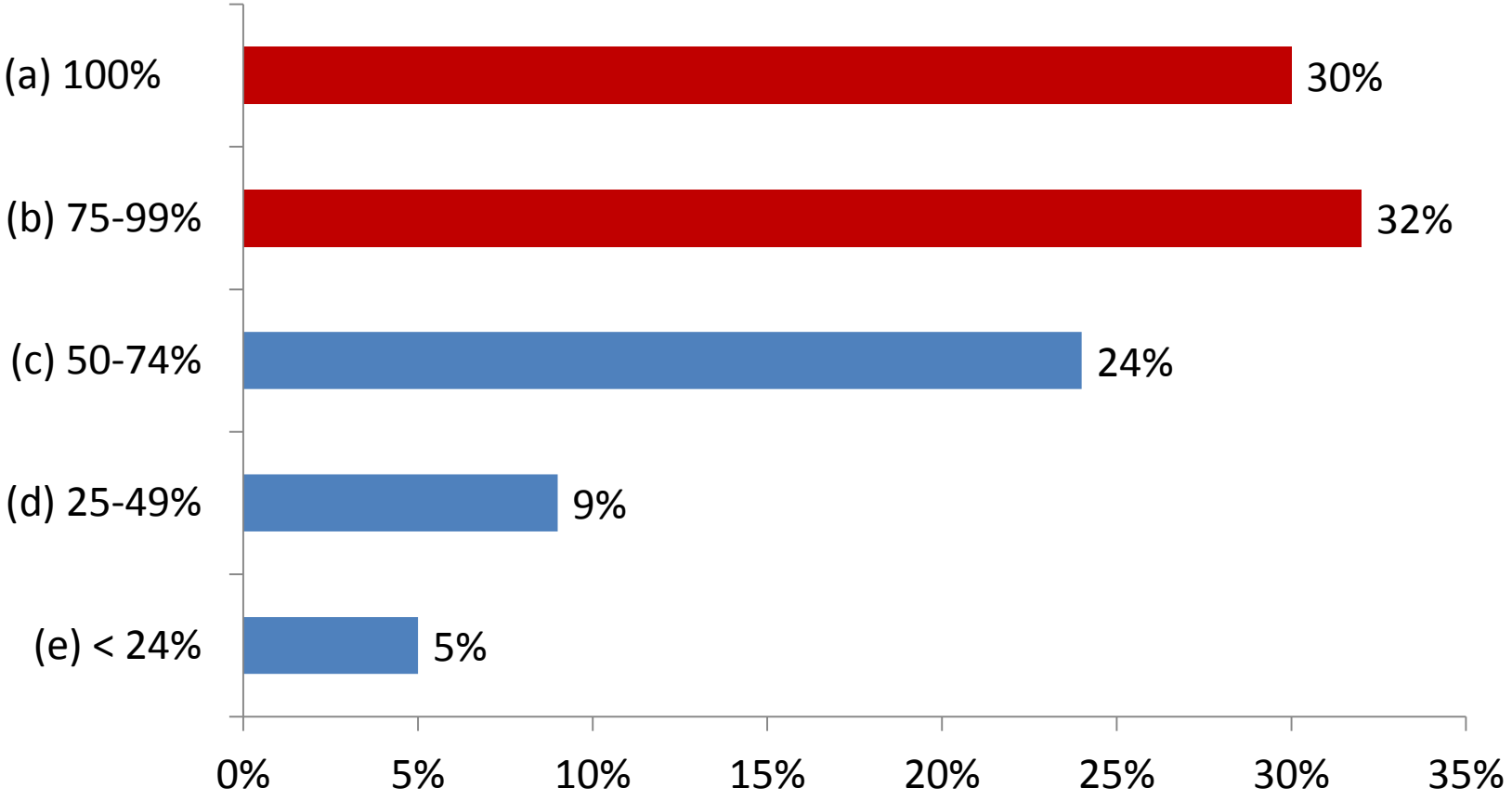
- How many people filled out the survey?
- We wanted MedCon's help, so we would like to get everyone's input on one important question.
- This is how we will accomplish this.
- We are going to give each table four tasks.

1. Introductions: Each person should state:
    - His/her name.
    - Title.
    - Number of years in the field.
2. Determine Roles
    - Person with the most experience is the chair.
    - Person with the least experience is the recorder.
3. Using the form on the table:
    - The chair will lead a discussion on whether it would be helpful for companies if FDA ranked 483 observations as major non-conformances and minor non-conformances.
    - The group should come up with three reasons to support its conclusion.
    - The recorder should list the responses on the form.
4. We will use the input when we discuss the last question of the survey, which is question 10 and then provide the forms to FDA.

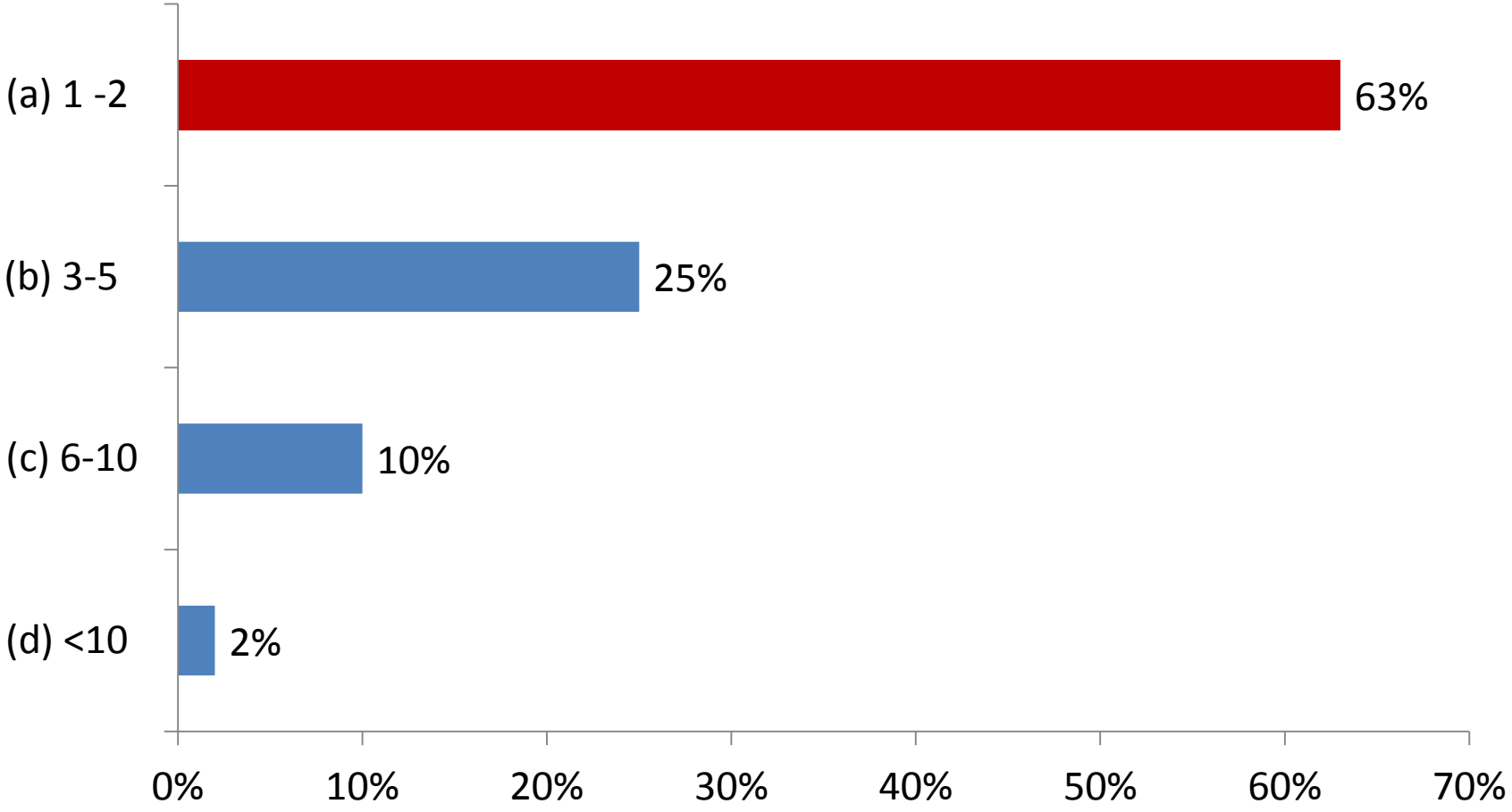
Limitations of Survey

- Numerous organizations sent the survey out to their mailing lists.
- There was no control on who filled out the survey.
- We want to use the results as a starting point for discussion.
- Organizations should not use the data as concrete evidence of the opinions of the medical device industry.

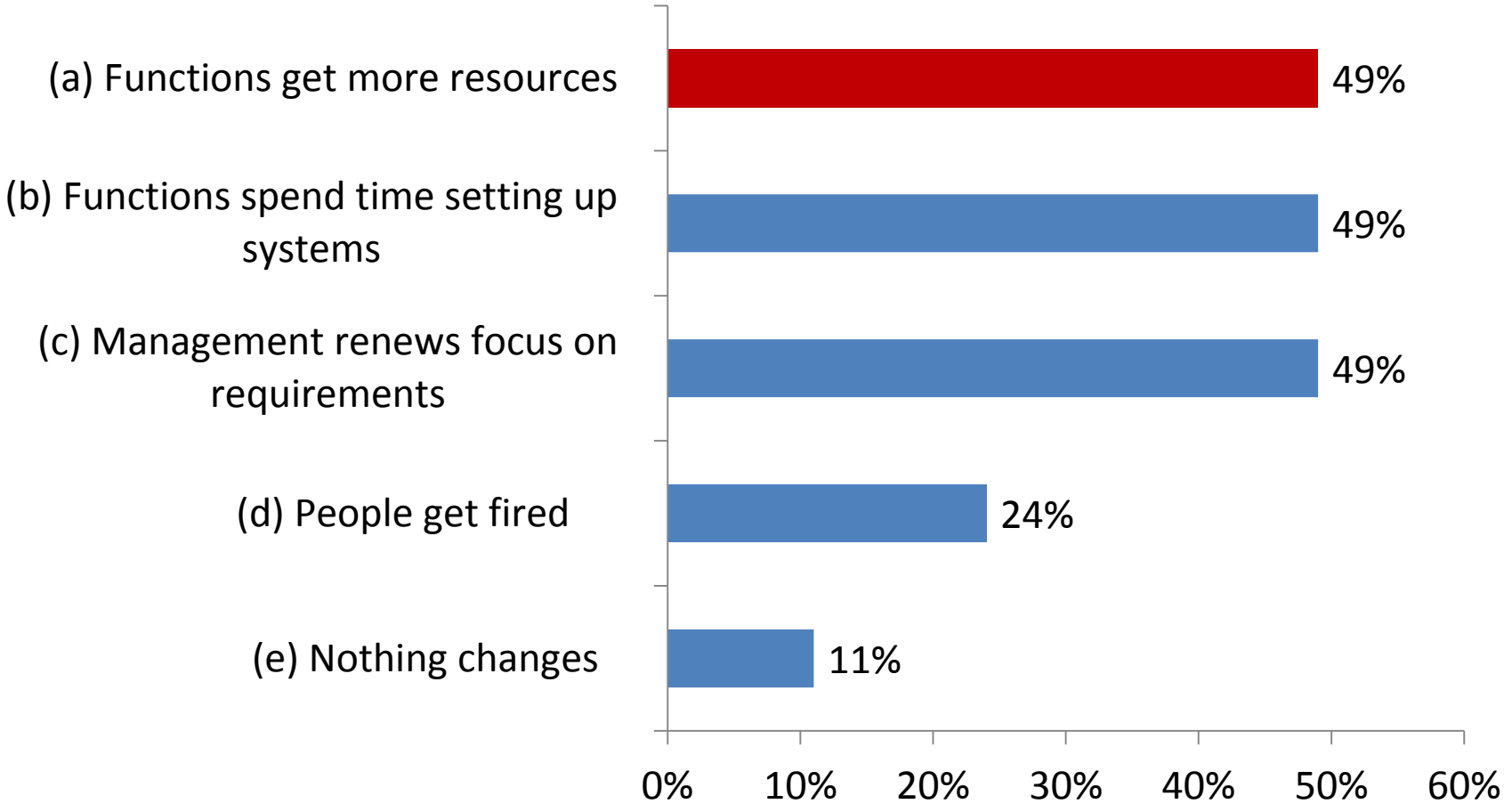
1. How often do 483 observations force your management to focus on process that affect product quality?



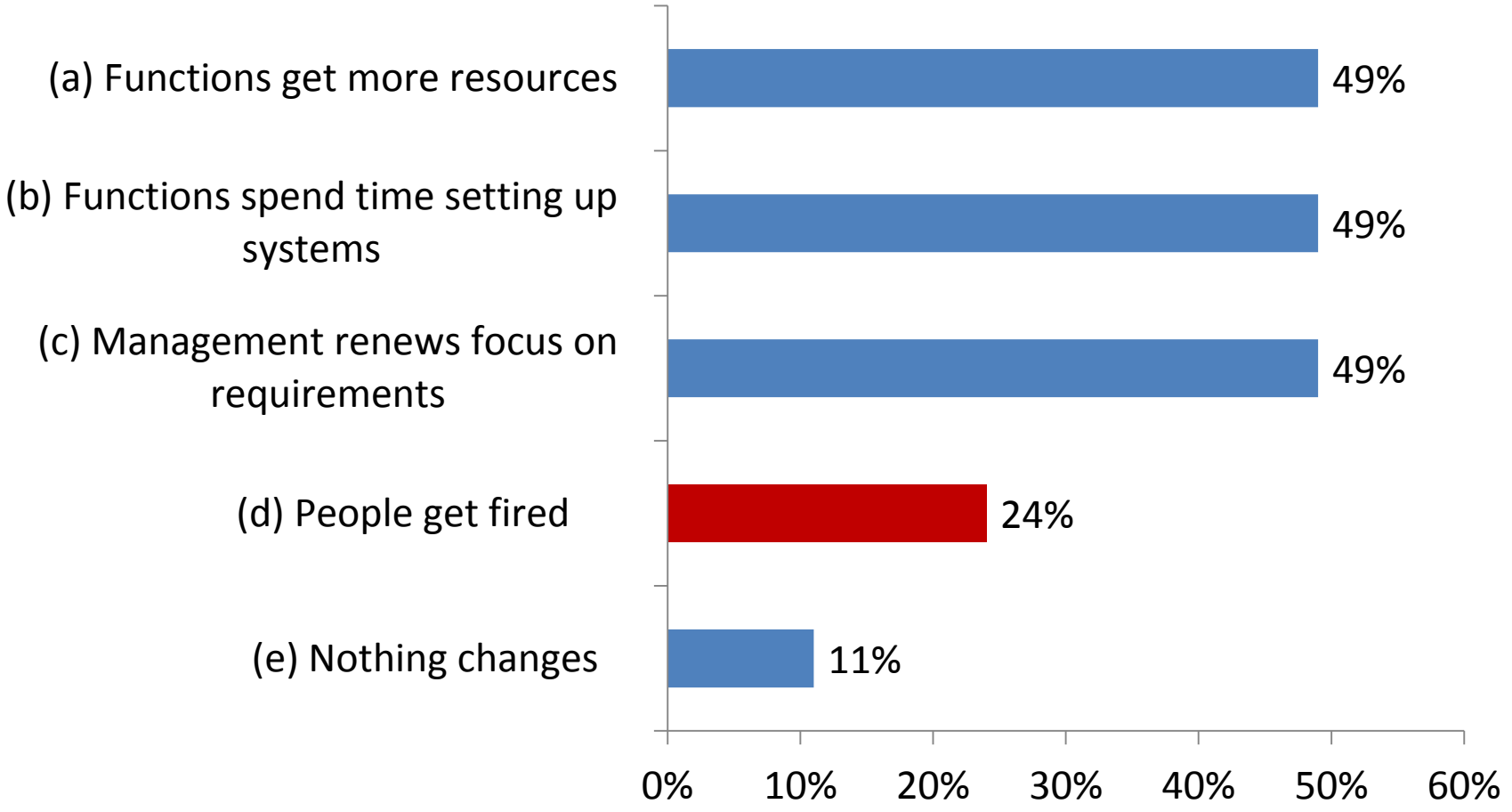
2. How many 483 observations does your firm have to get before management perceives there is a problem?



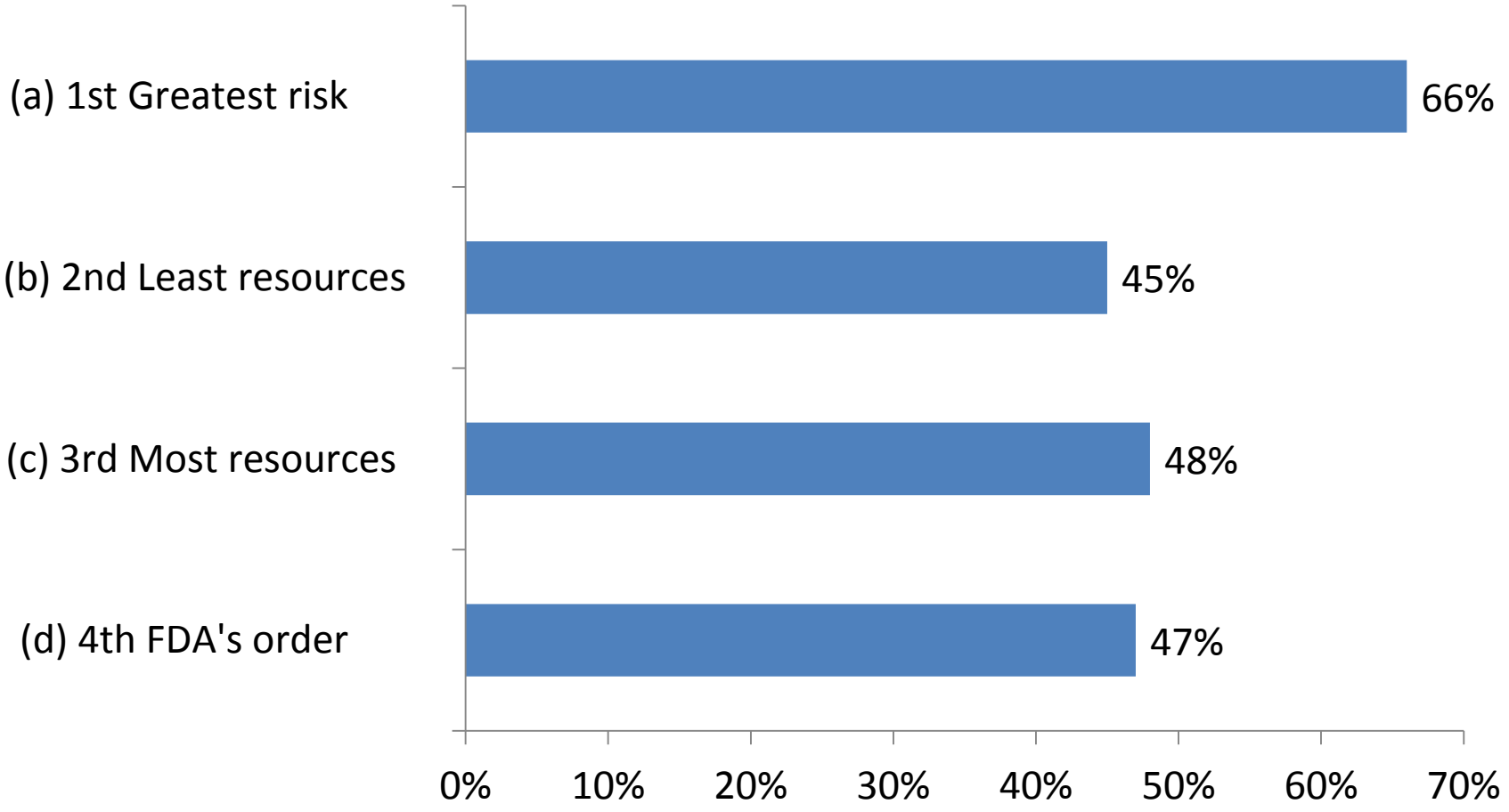
3. Which of the following actions do you believe generally result from 483 observations?



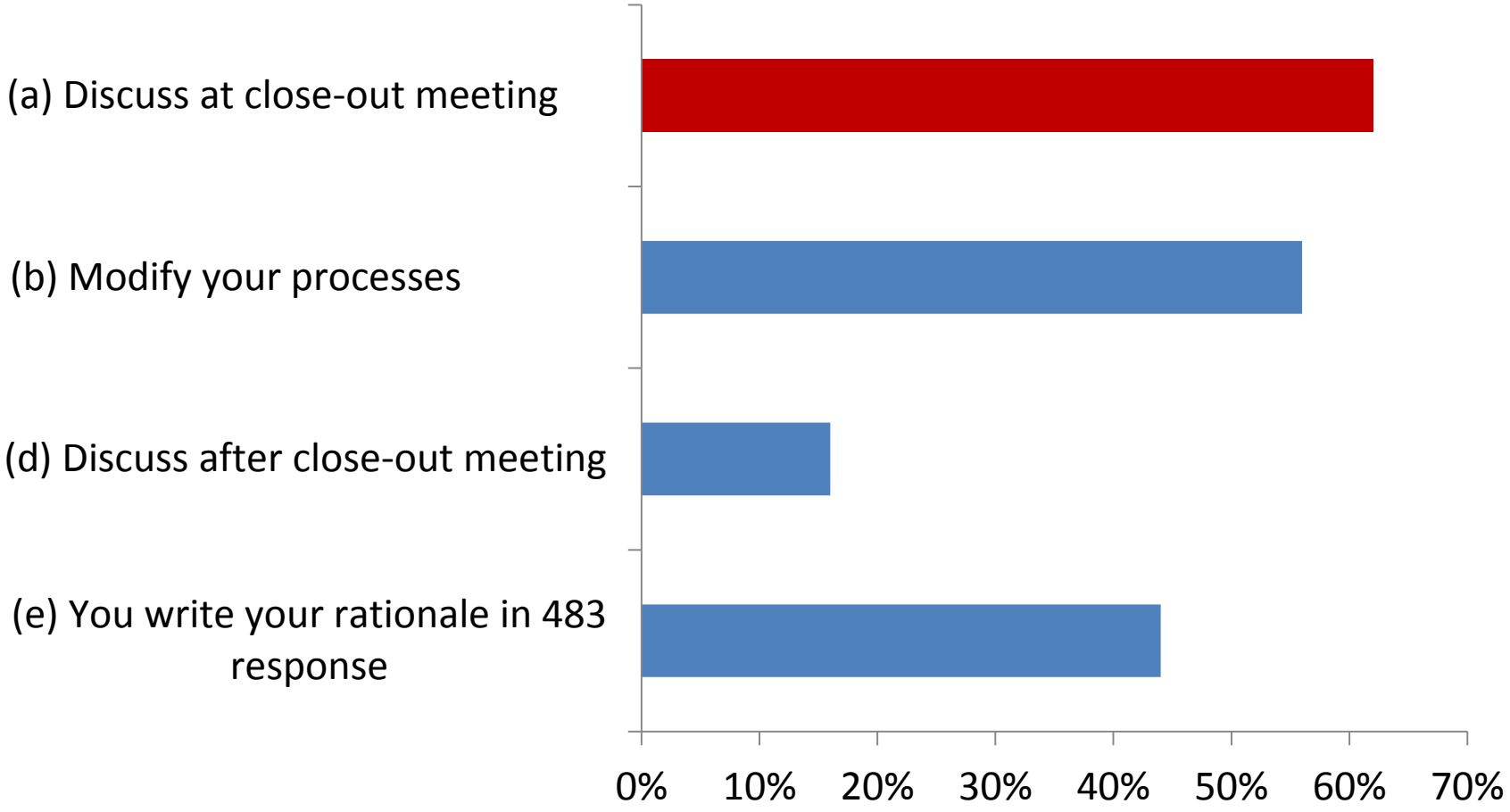
4. Which of the following actions do you believe generally result from 483 observations?



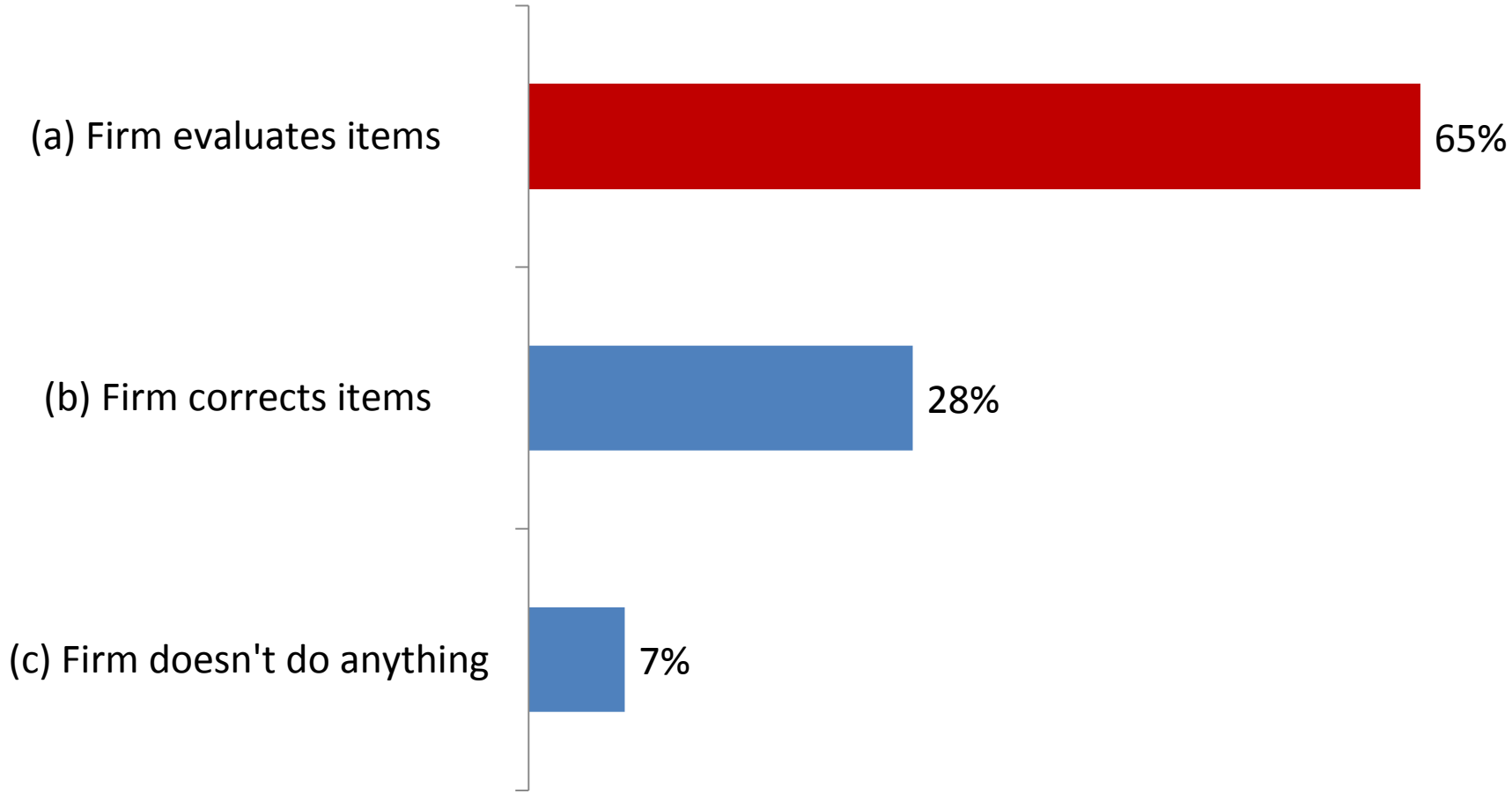
5. When a firm receives a number of 483 items, rank order in which it takes corrective action.



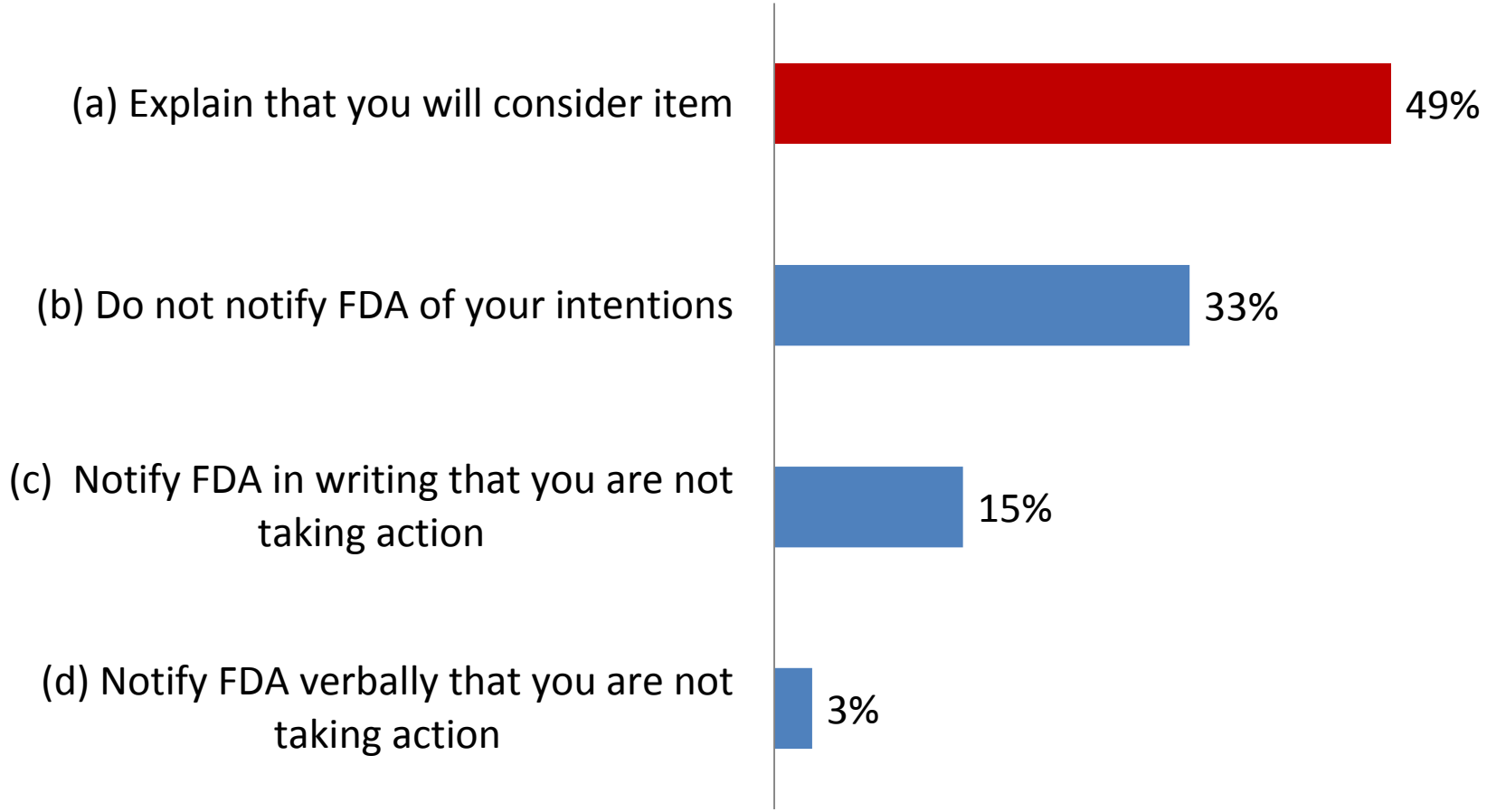
6. How do you handle a minor 483 observation with which you don't agree?



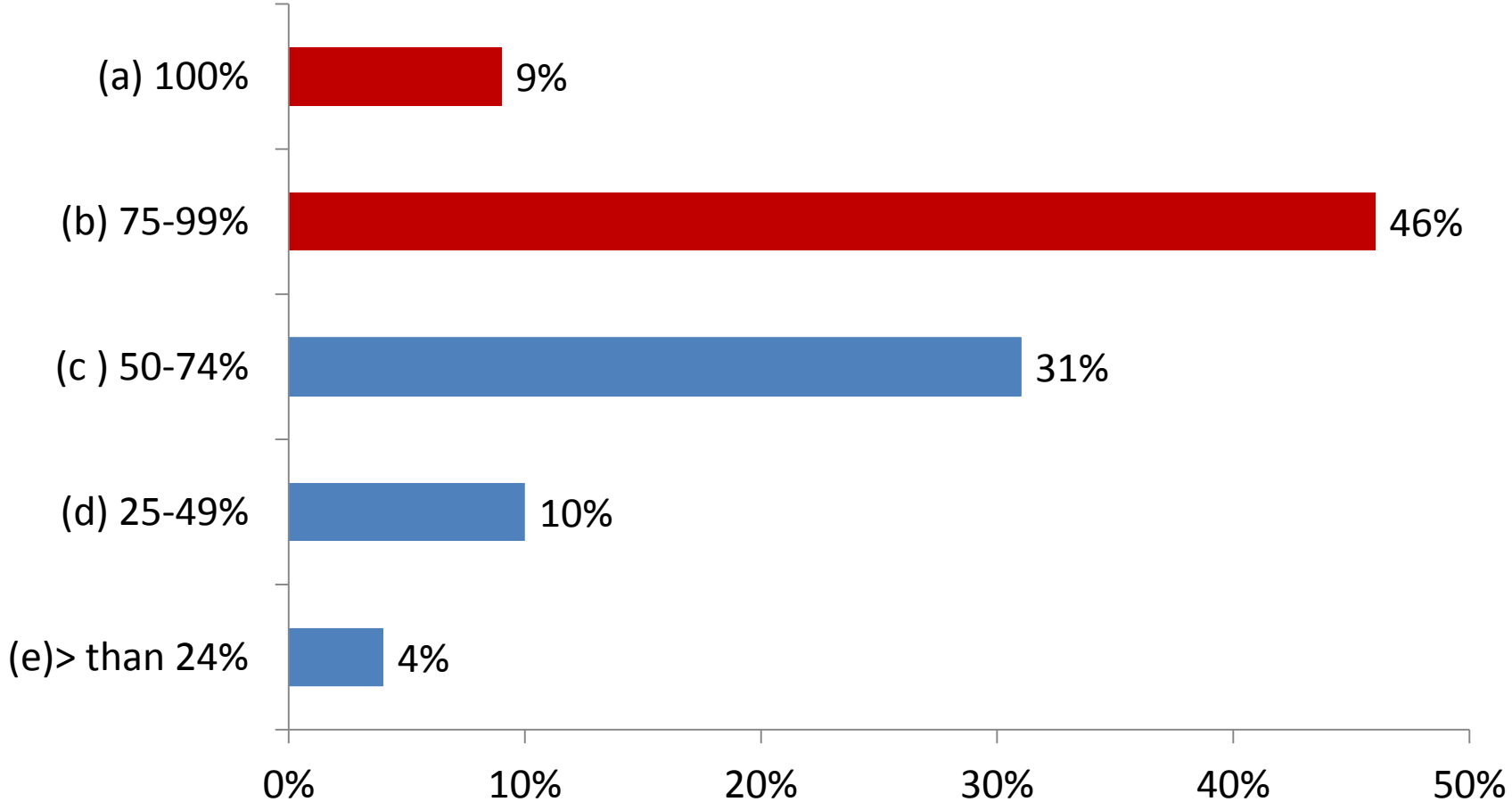
7. How does your firm view taking action in regard to discussion items.



8. If your firm is not going to address a discussion item, which of the following action do you take?



9. In general, do you think that 483 observations clearly define problems so firms can take corrective action?



10. Do you think ranking 483 observations as major non-conformance and minor non-conformance would help you apply resources appropriately?