

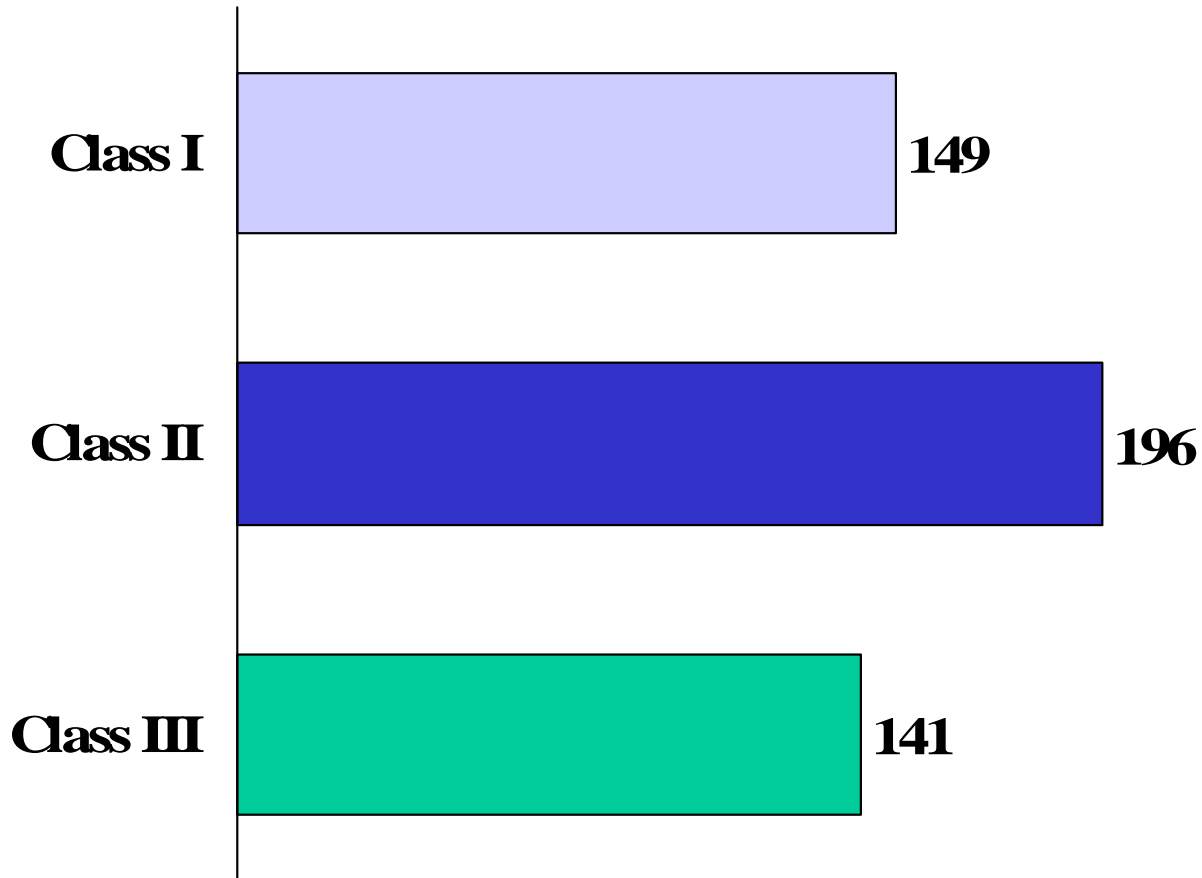
# How Medical Device Firms Are Conducting Management Reviews

Nancy Singer, Compliance-Alliance

# Compliance-Alliance Sent Out a Survey

- 301 firms filled it out
- Response rate was higher than other surveys
- 90 individuals expressed interest in doing further benchmarking work

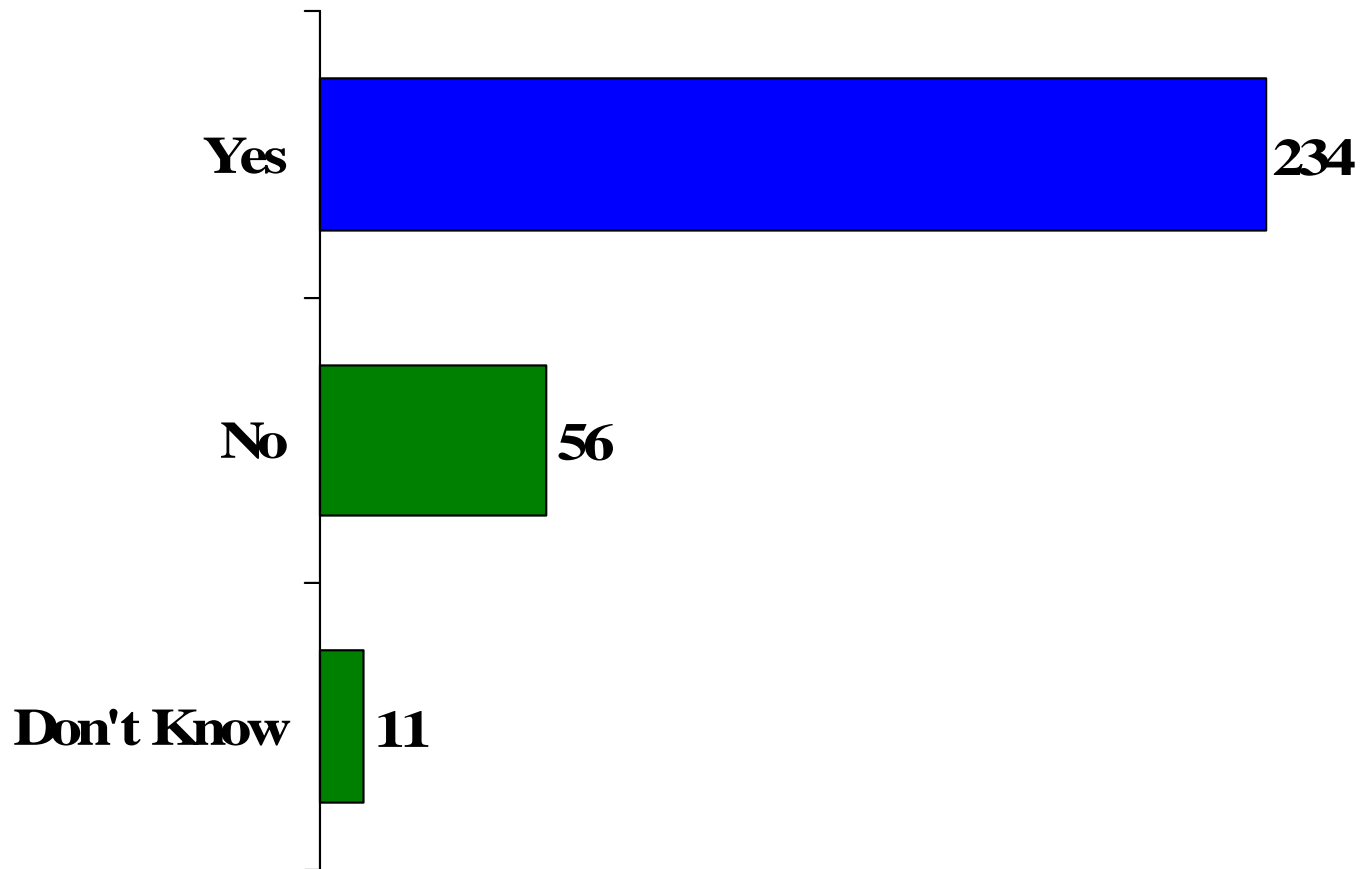
# Classes of Devices Represented



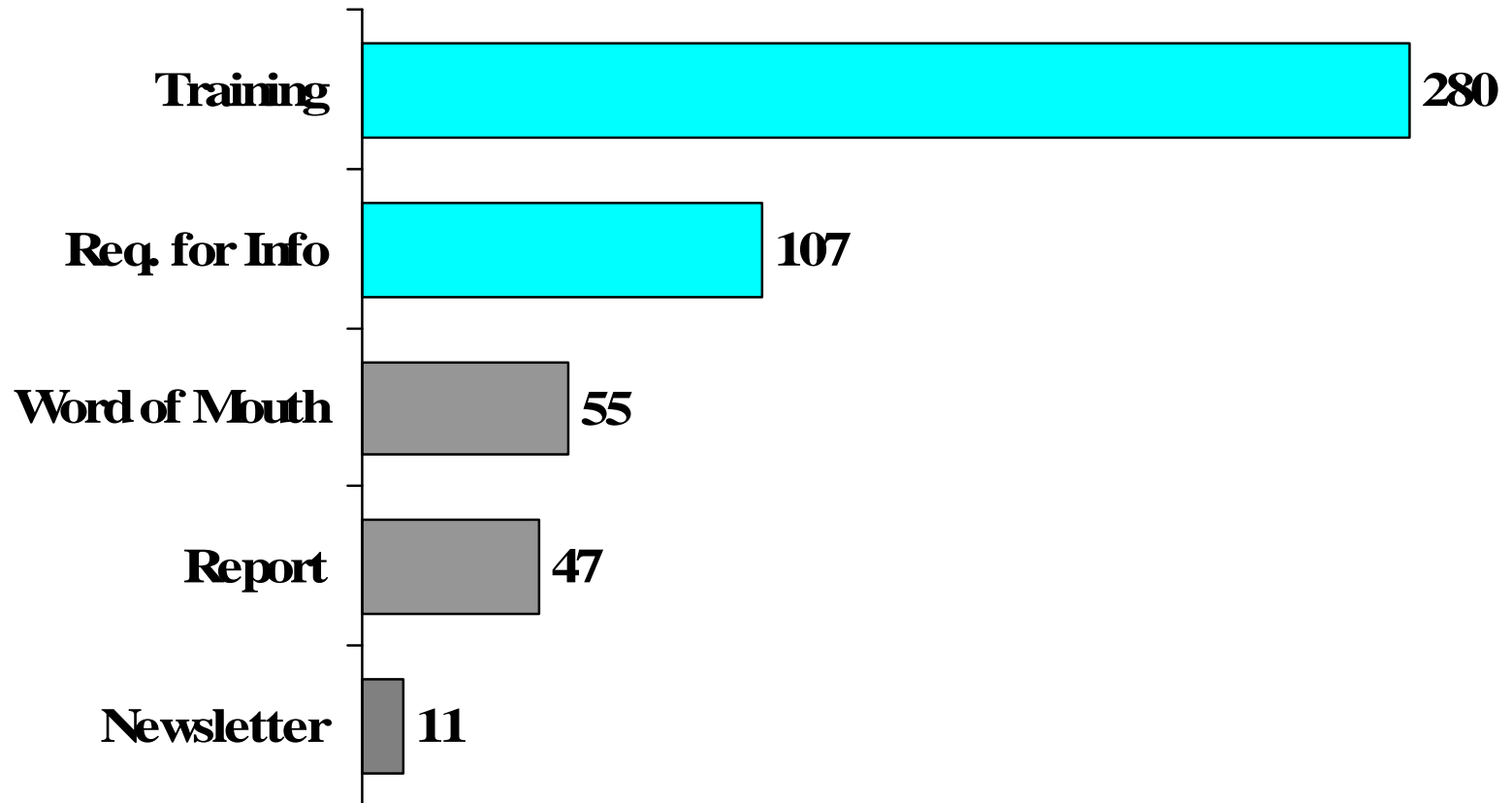
\* Firms manufactured more than 1 class of devices

Is the Review Important and Is It  
on the Company's Radar Screen?

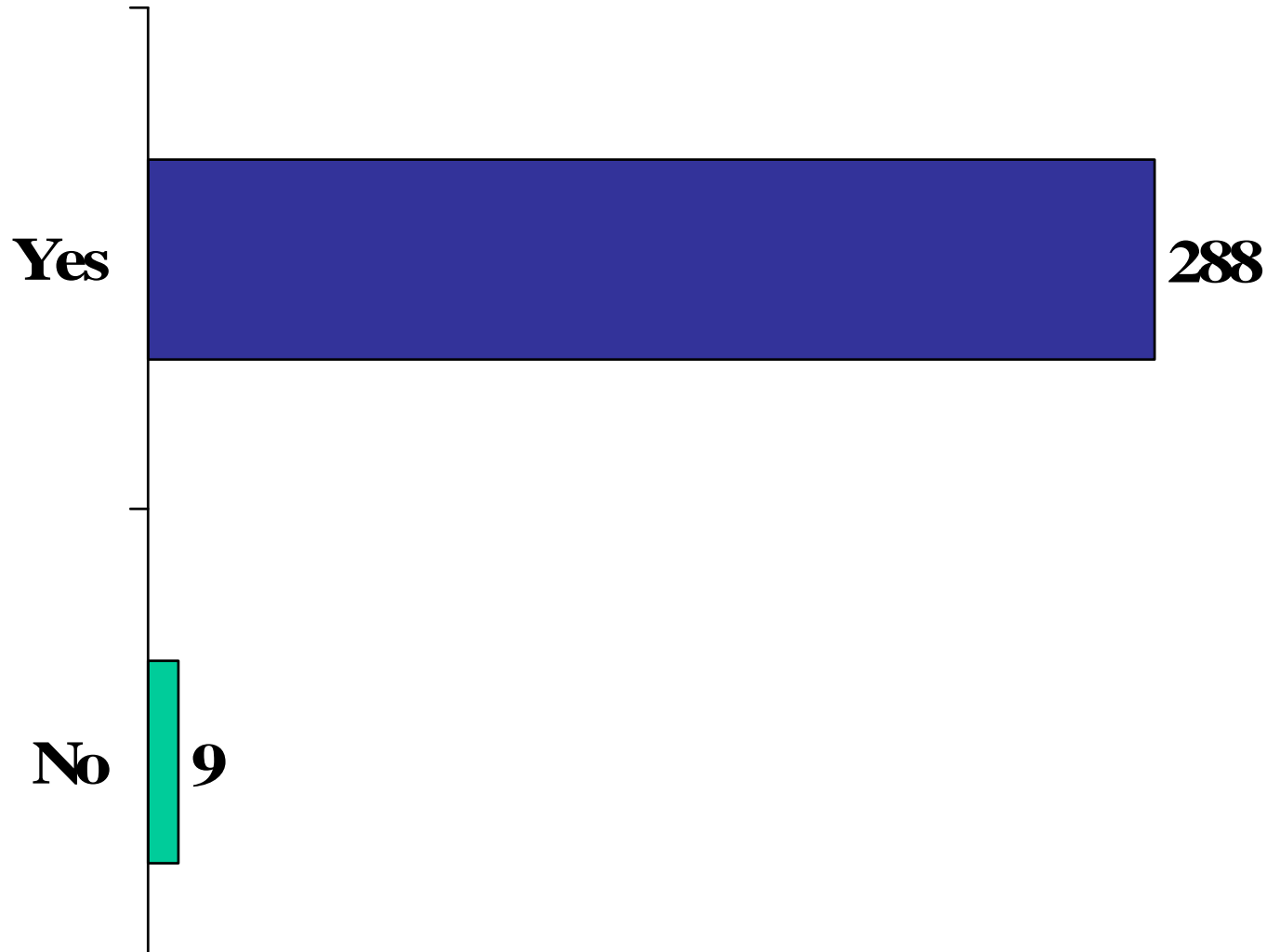
Do employees understand that senior management conducts management reviews?



# How do people learn about the reviews?

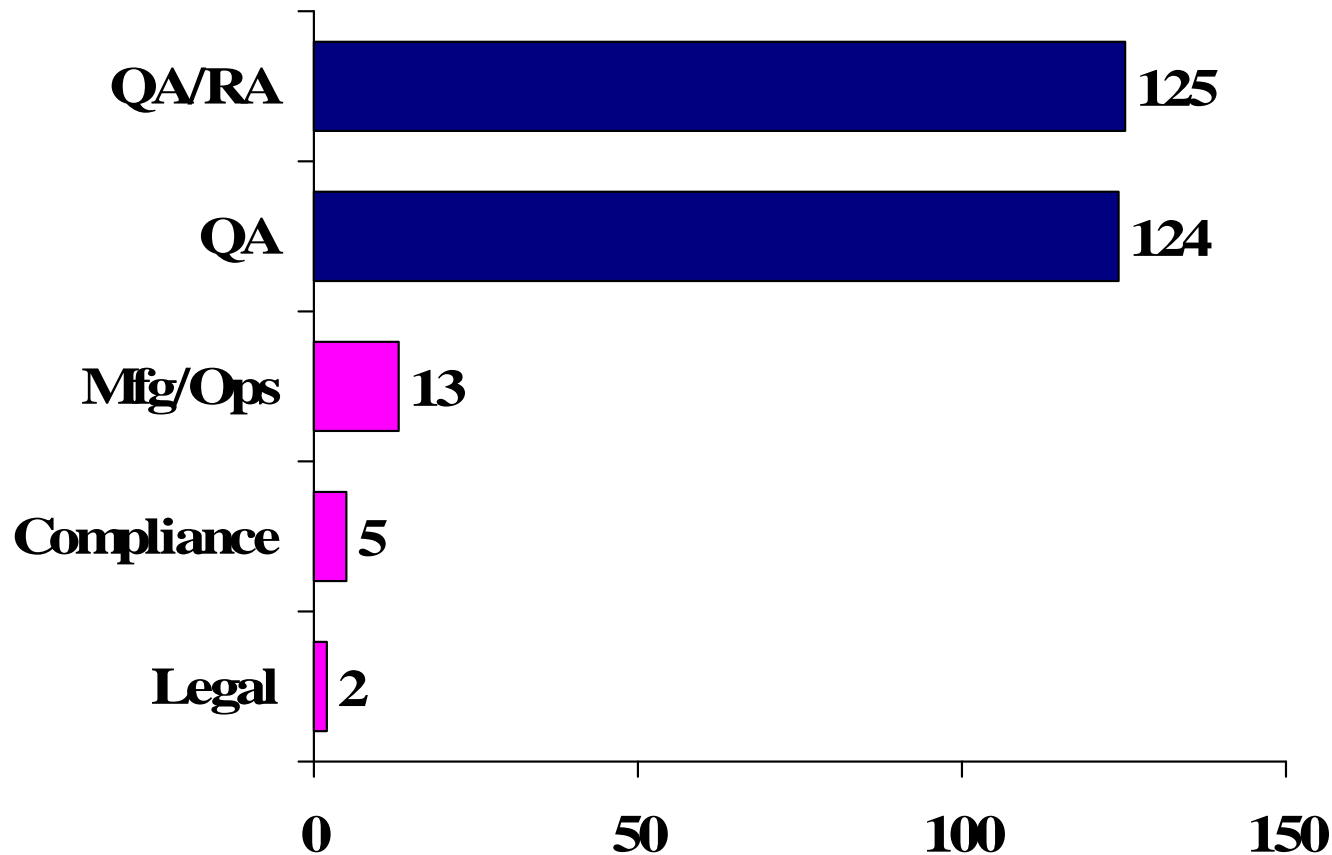


# Does your firm conduct reviews by holding a formal meeting?

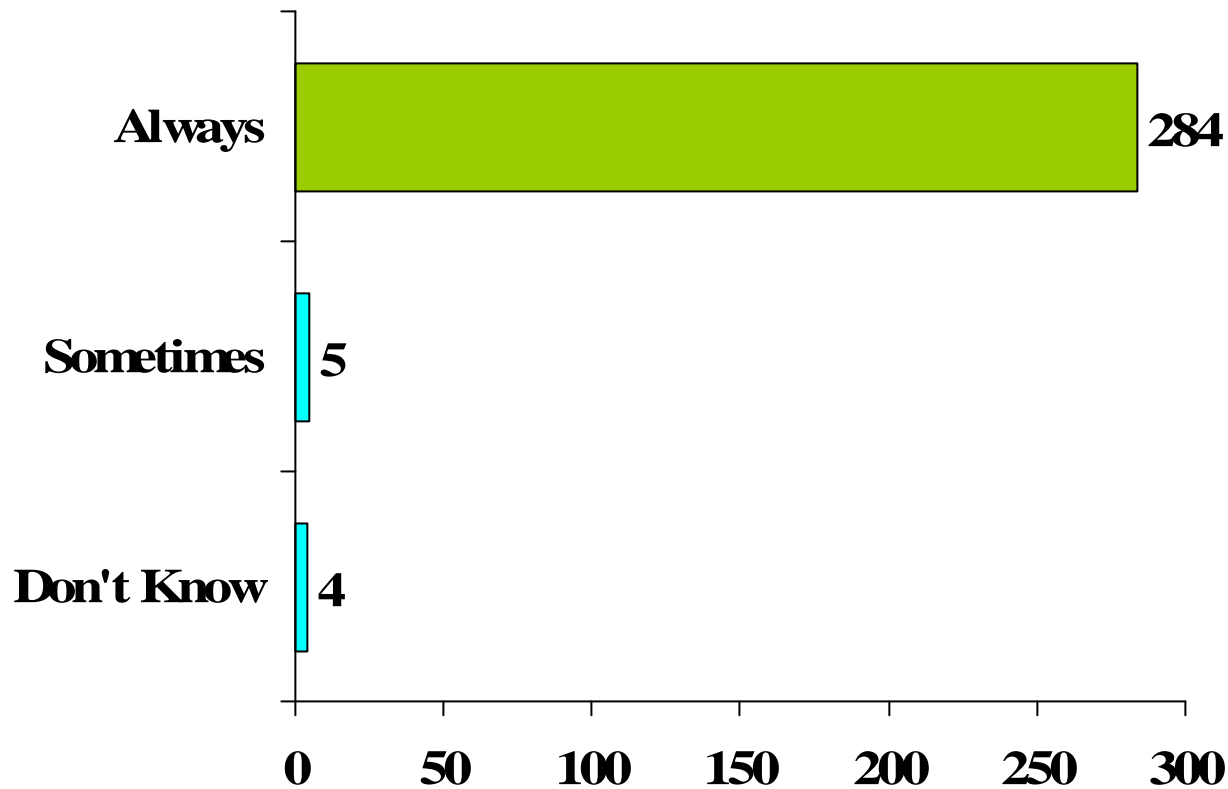


Who Attends the Reviews?

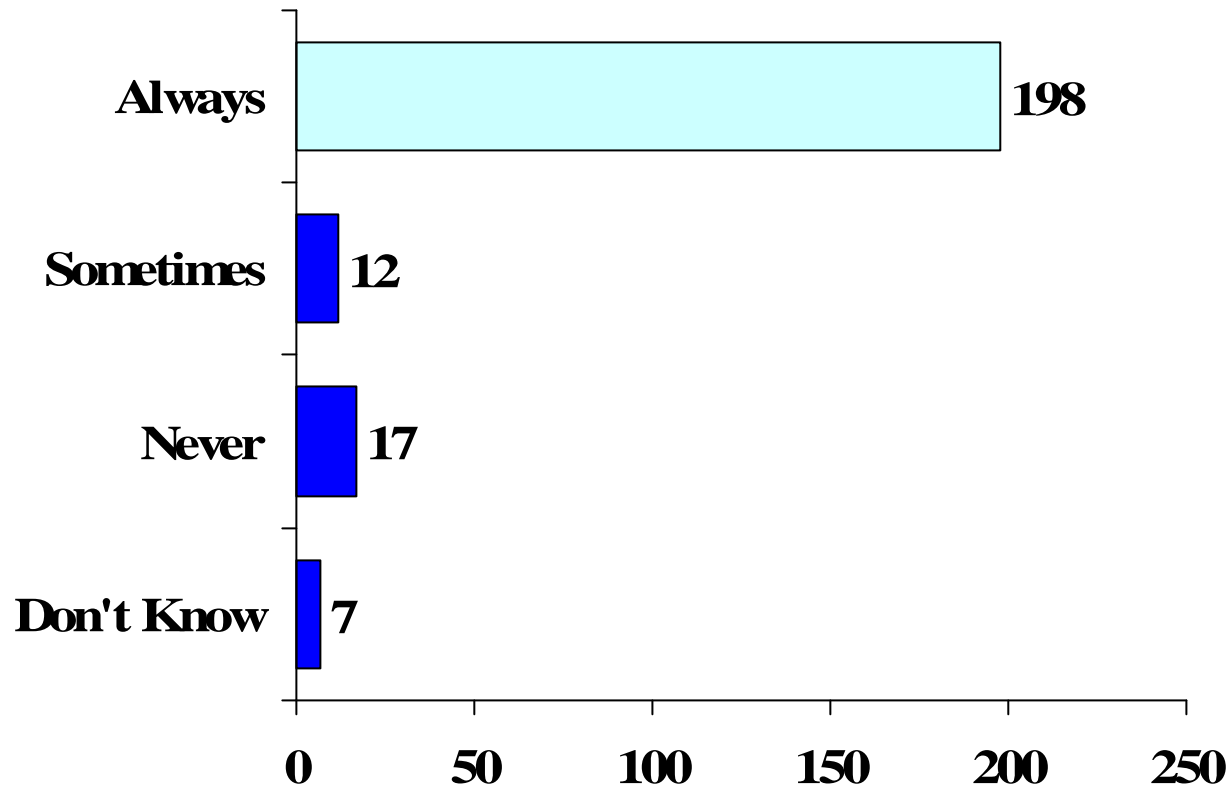
# What function within your firm serves as the management representative?



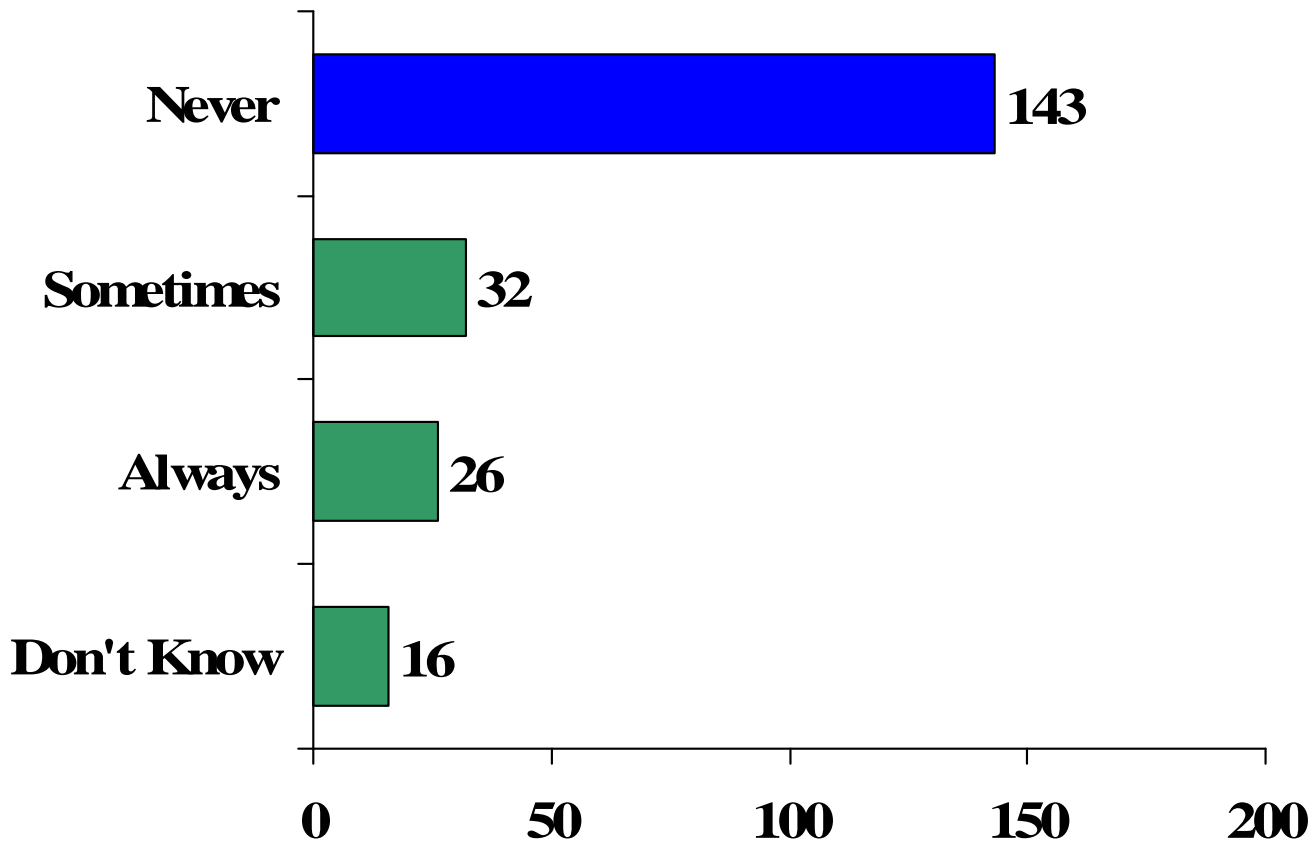
# How often does the management representative attend the review?



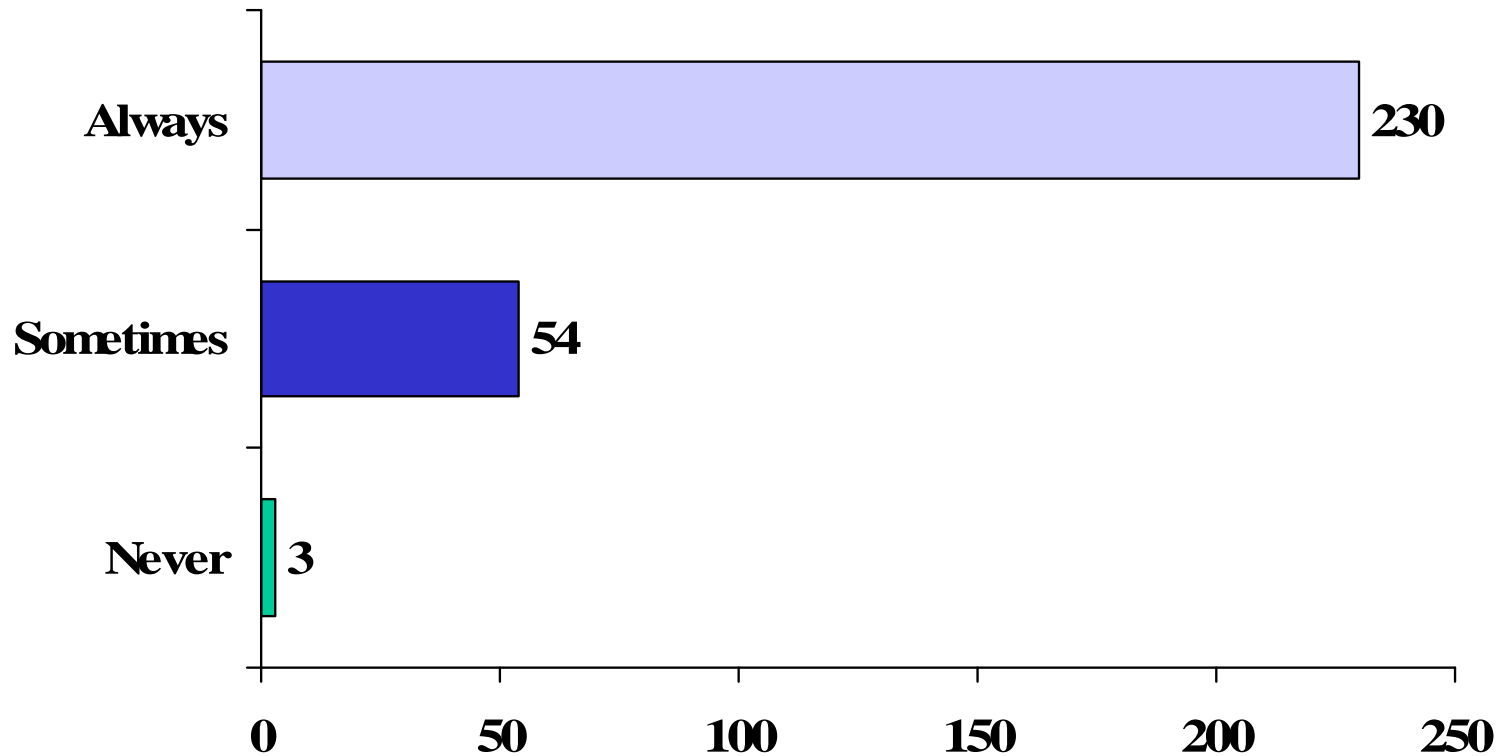
# How often does the president attend the review?



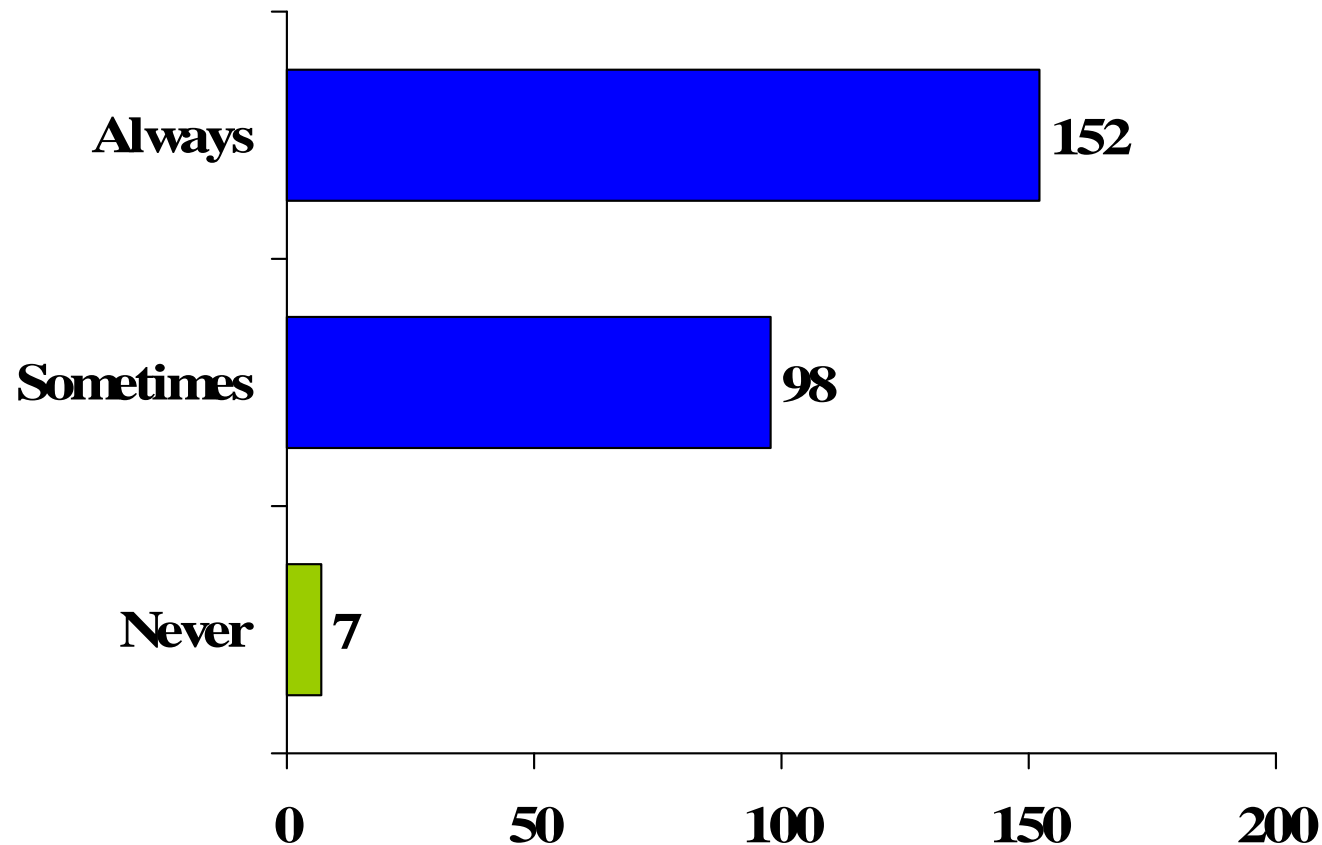
# How often do board members attend the review?



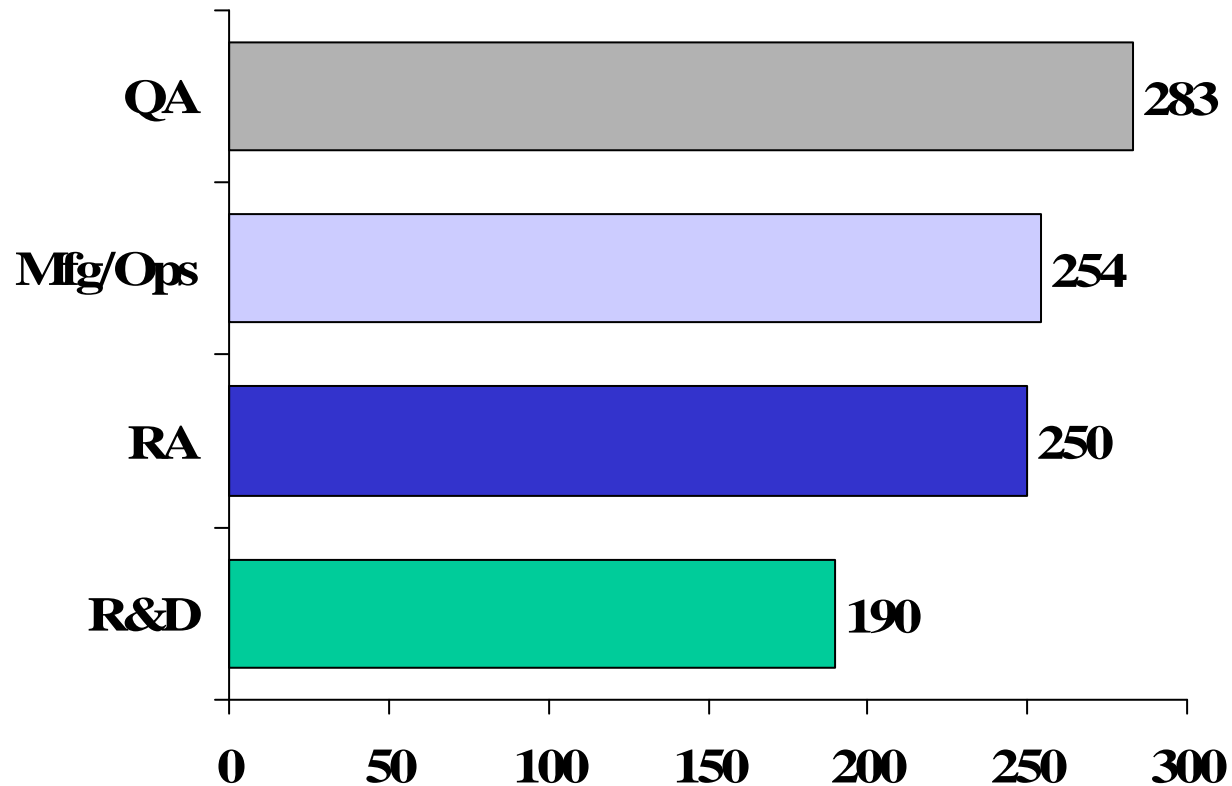
# How often do senior executives attend the review?



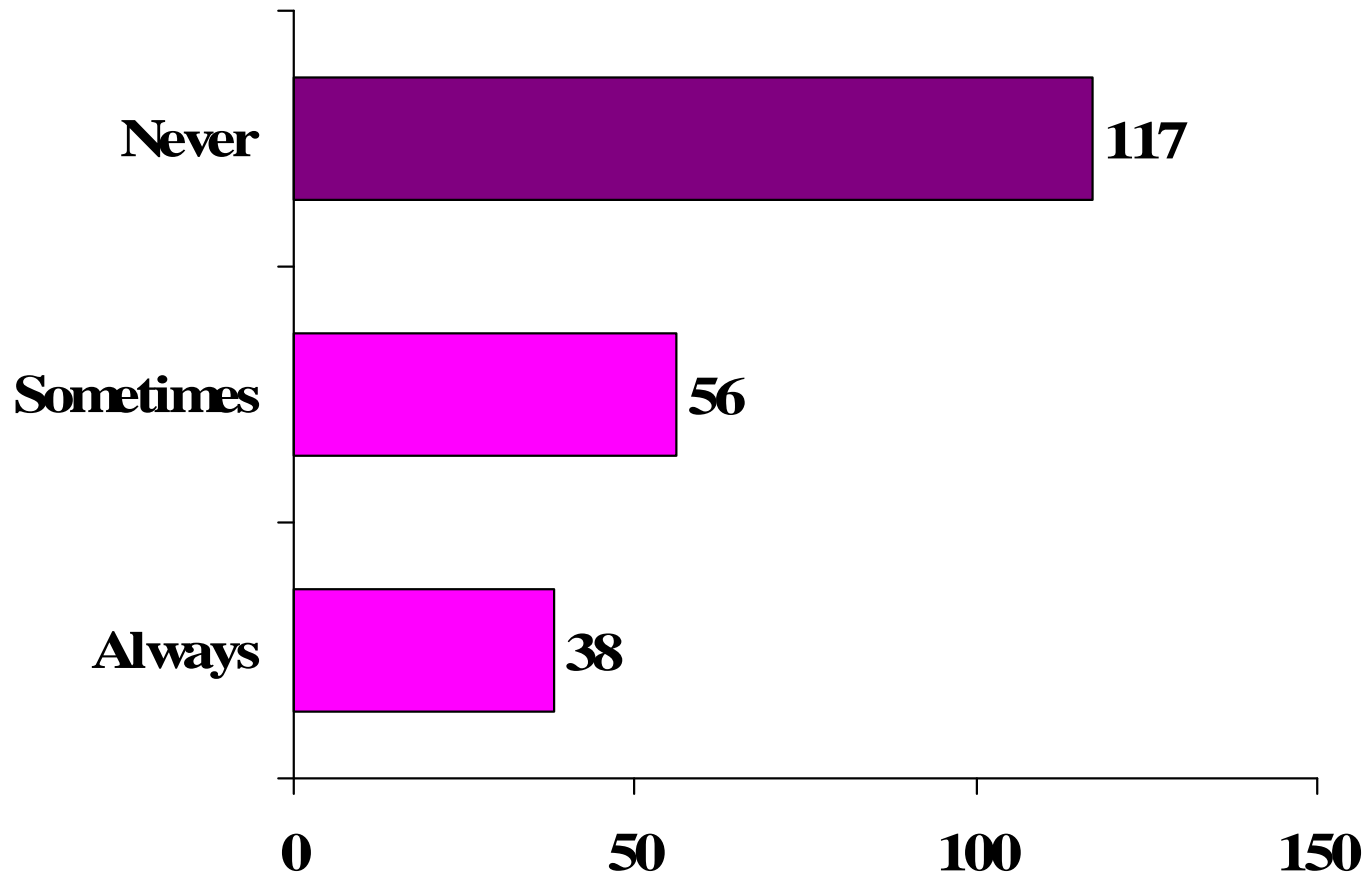
# How often do managers attend the review?



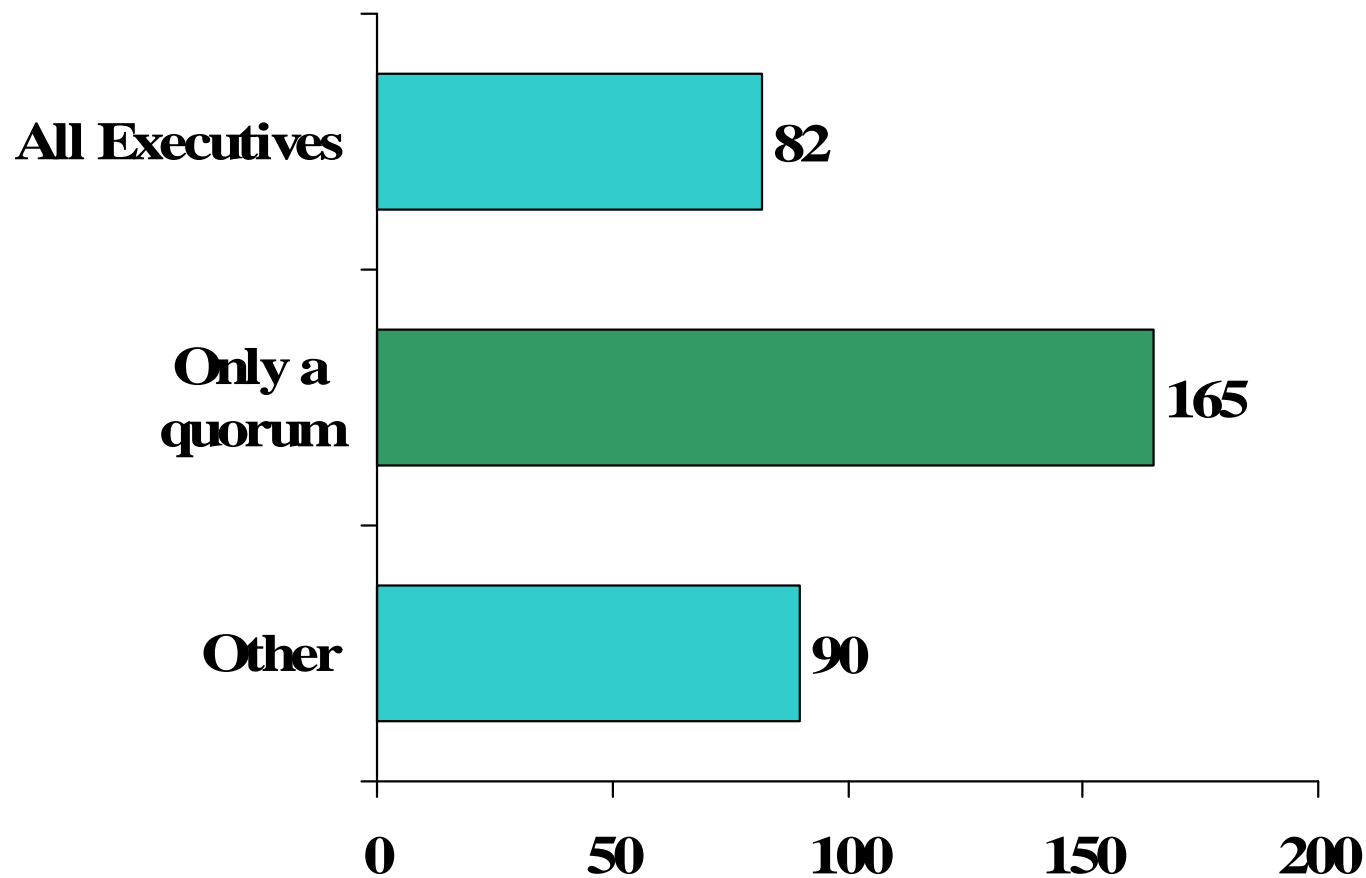
# What functions regularly attend the review?



# How often does the legal function attend the review?

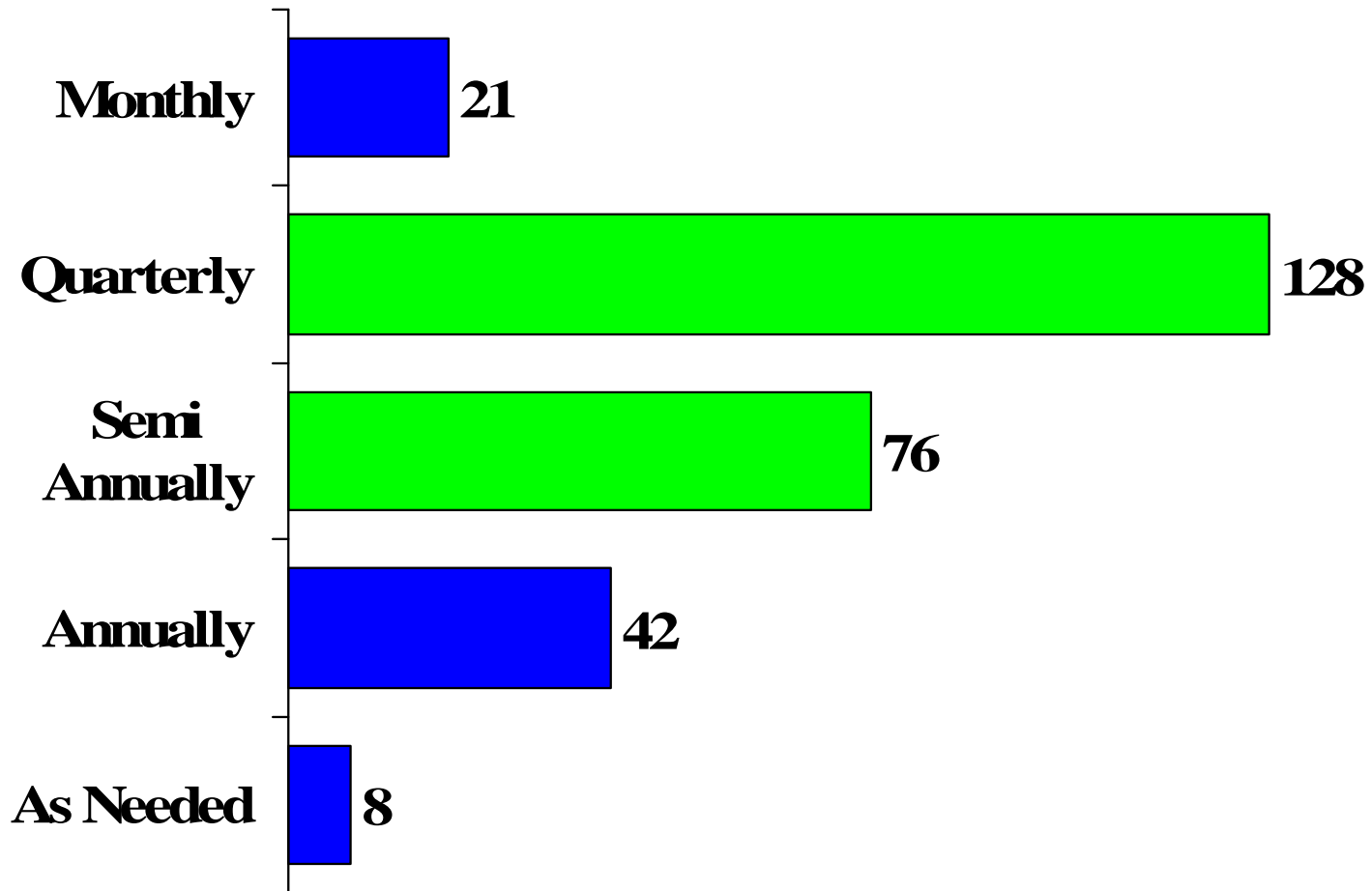


To have a review, what functions besides the management rep. need to be present?

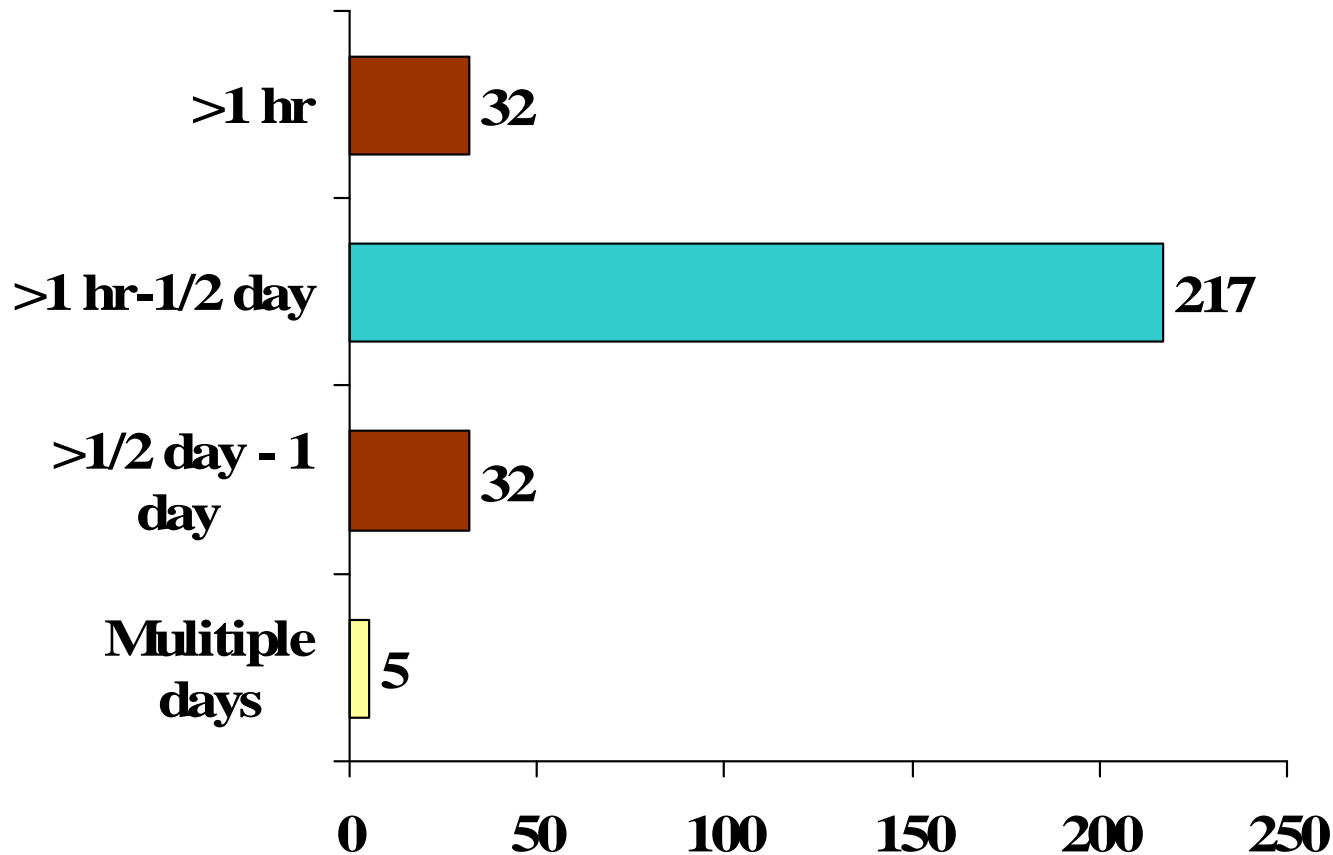


# How are Management Reviews Organized?

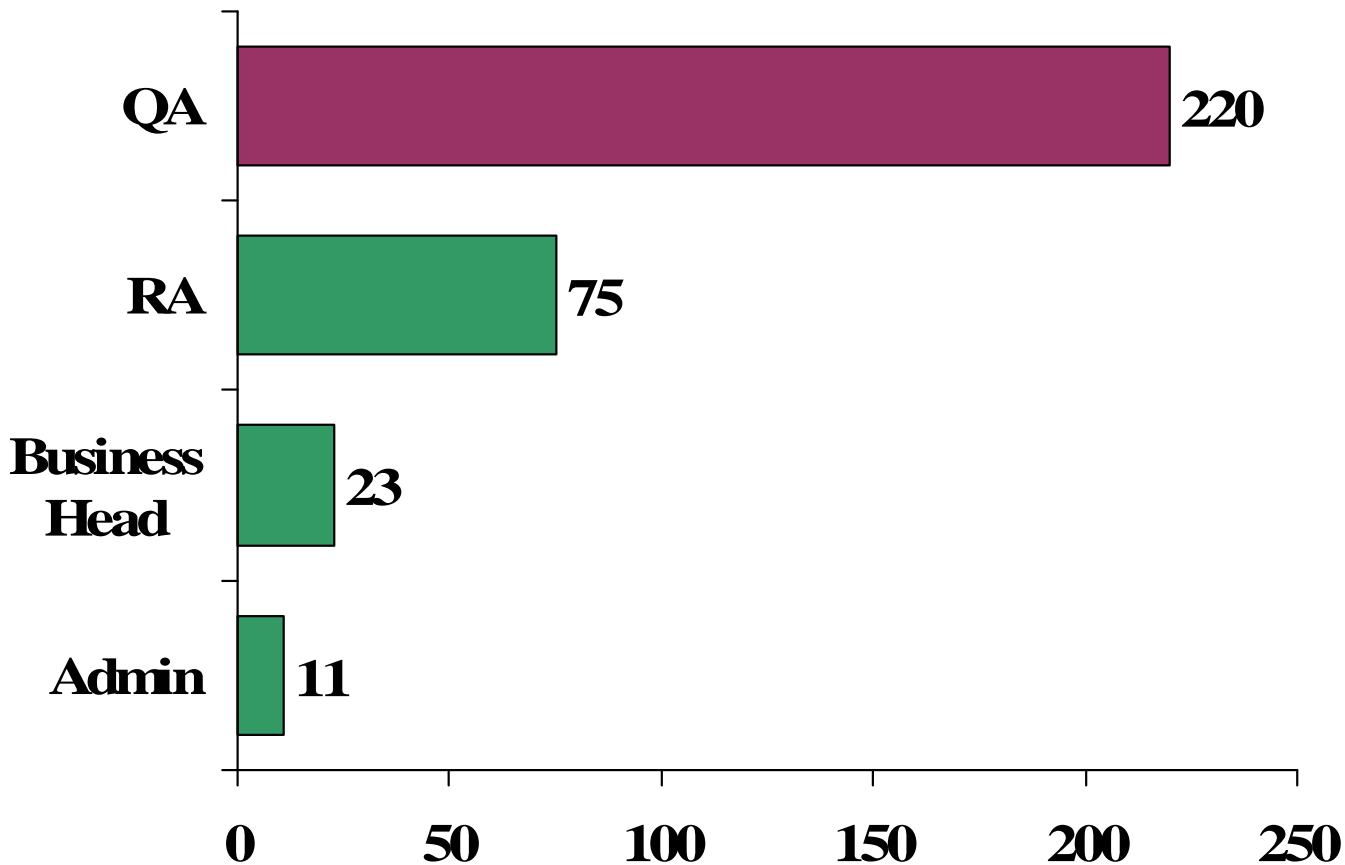
# How often does your firm conduct reviews?



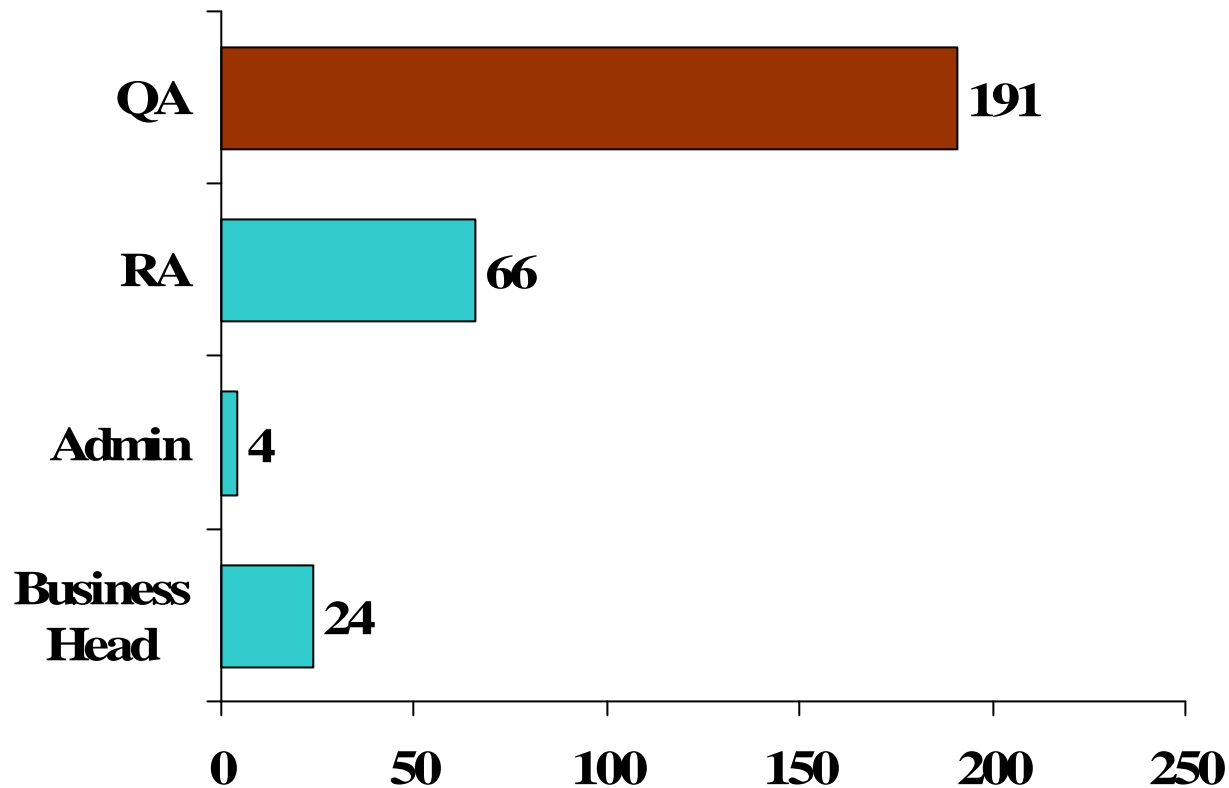
# How long does each review last?



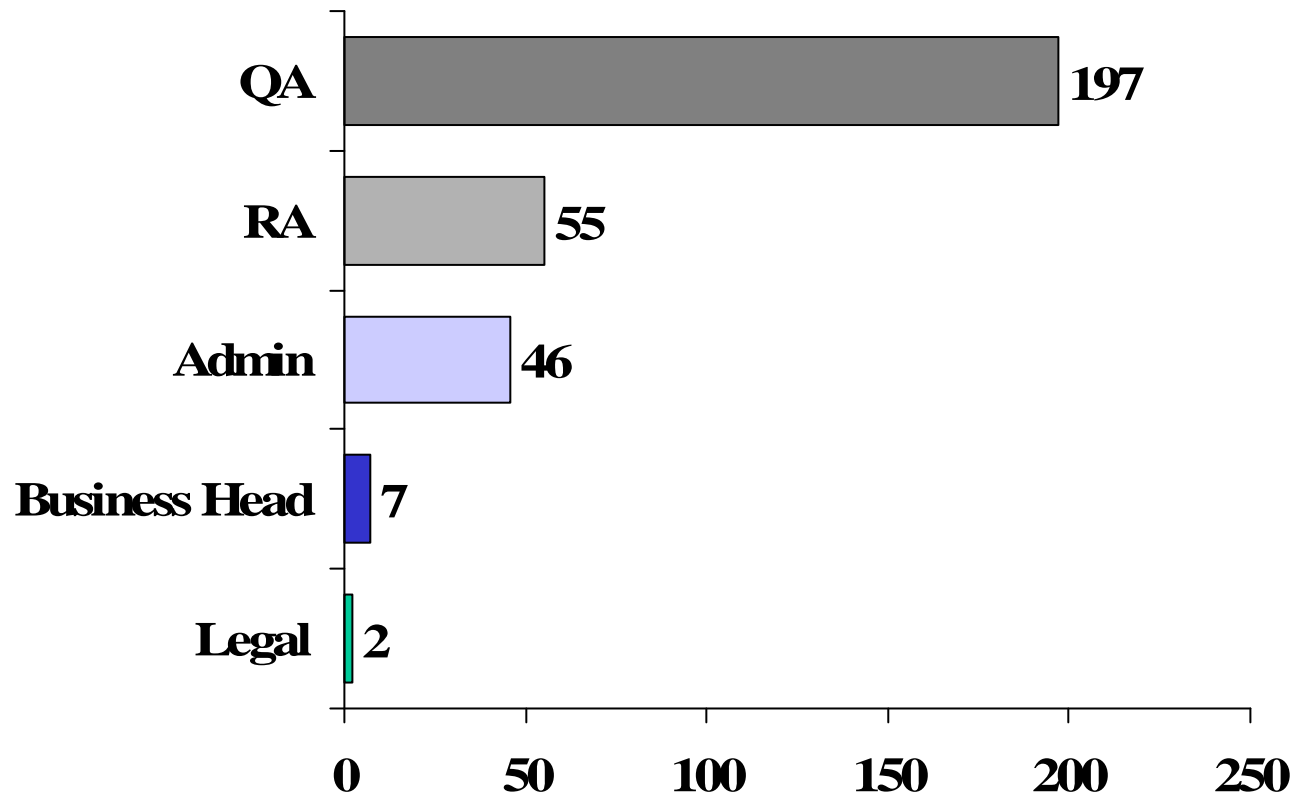
# Who is responsible for preparing an agenda?



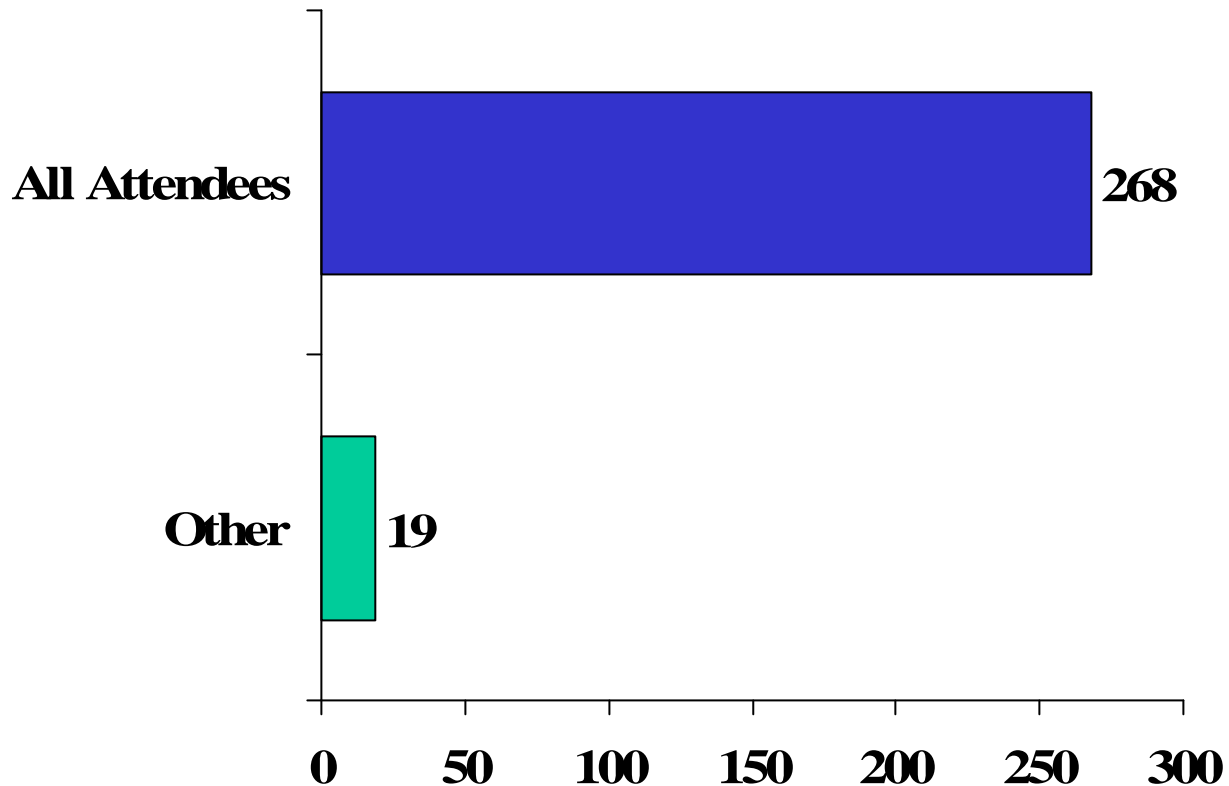
# Who is responsible for determining when the review will occur?



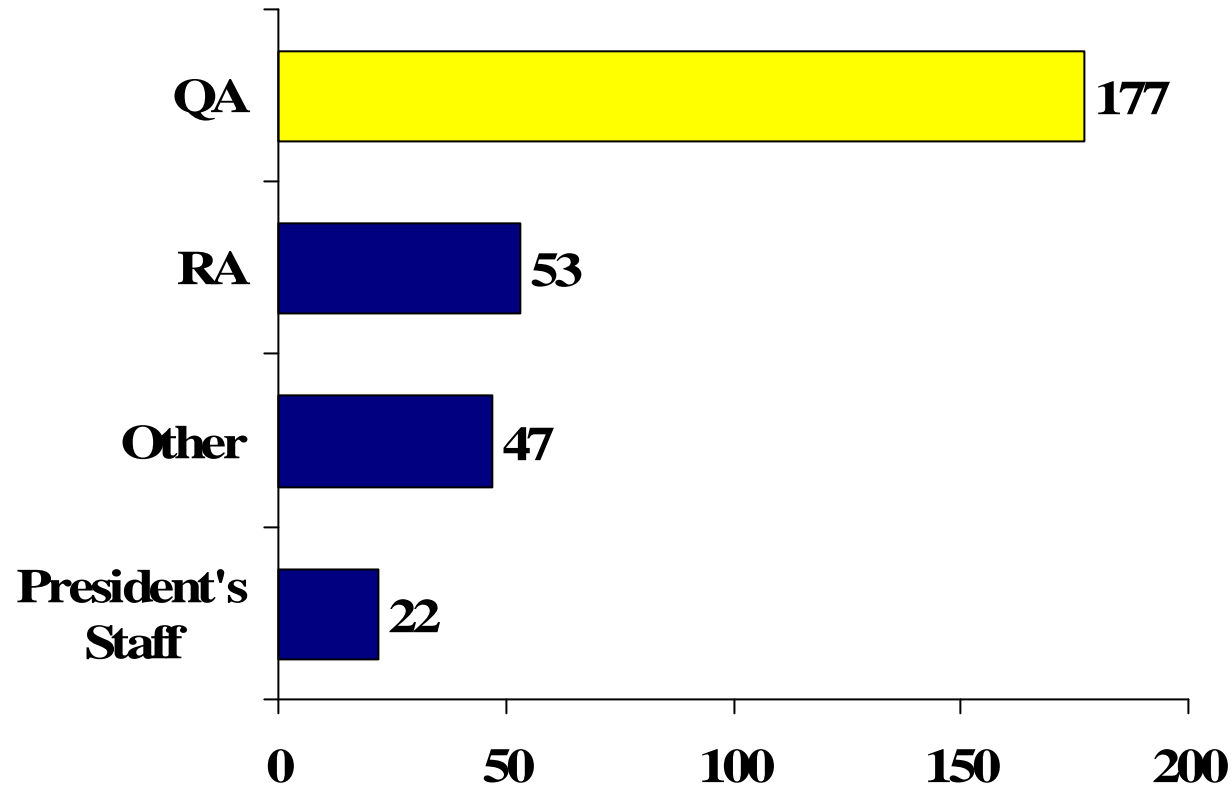
# Who is responsible for taking minutes during the review?



# Who can suggest modification to the minutes?

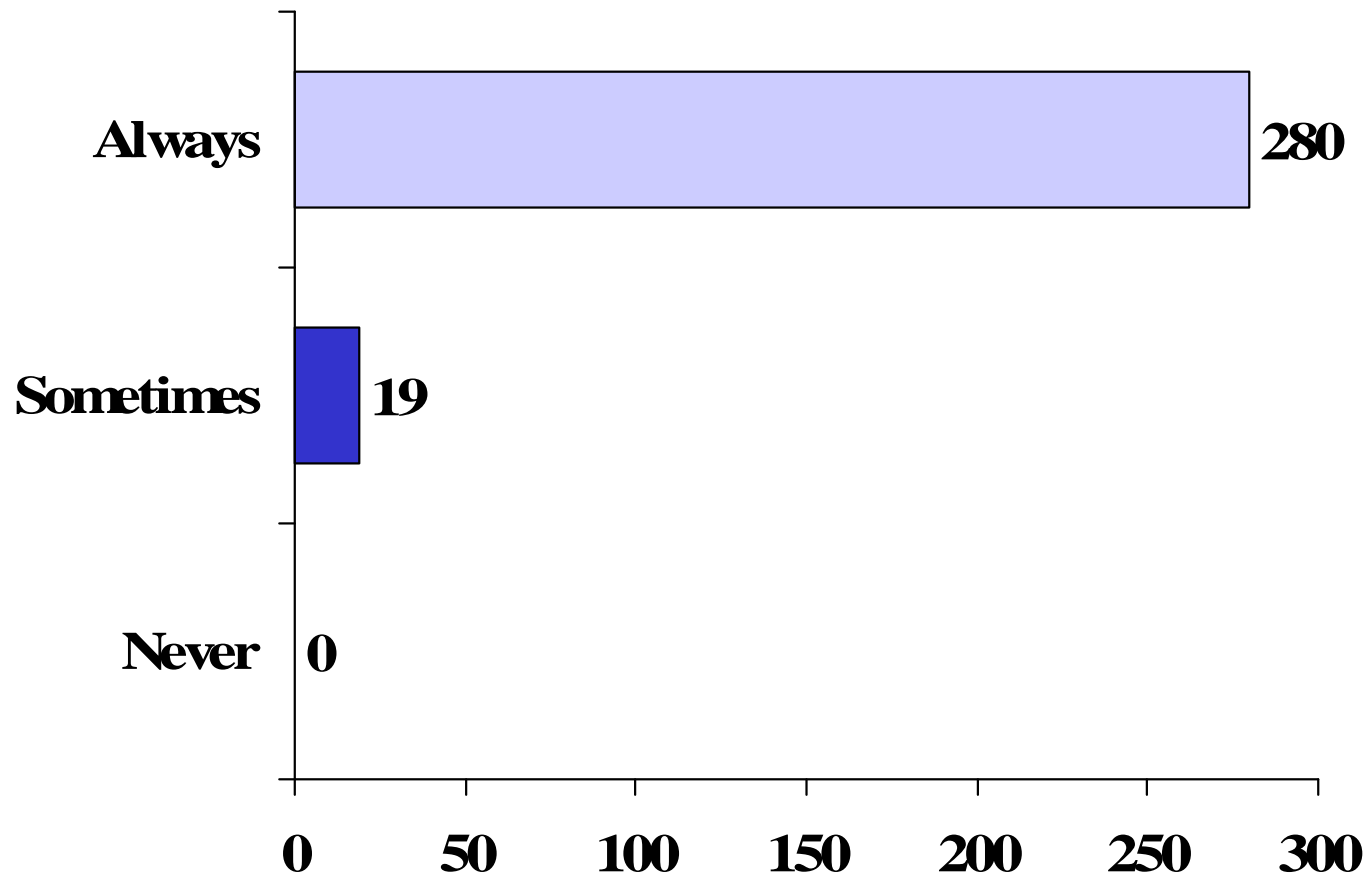


# Who is responsible for ensuring that follow-up issues are addressed?

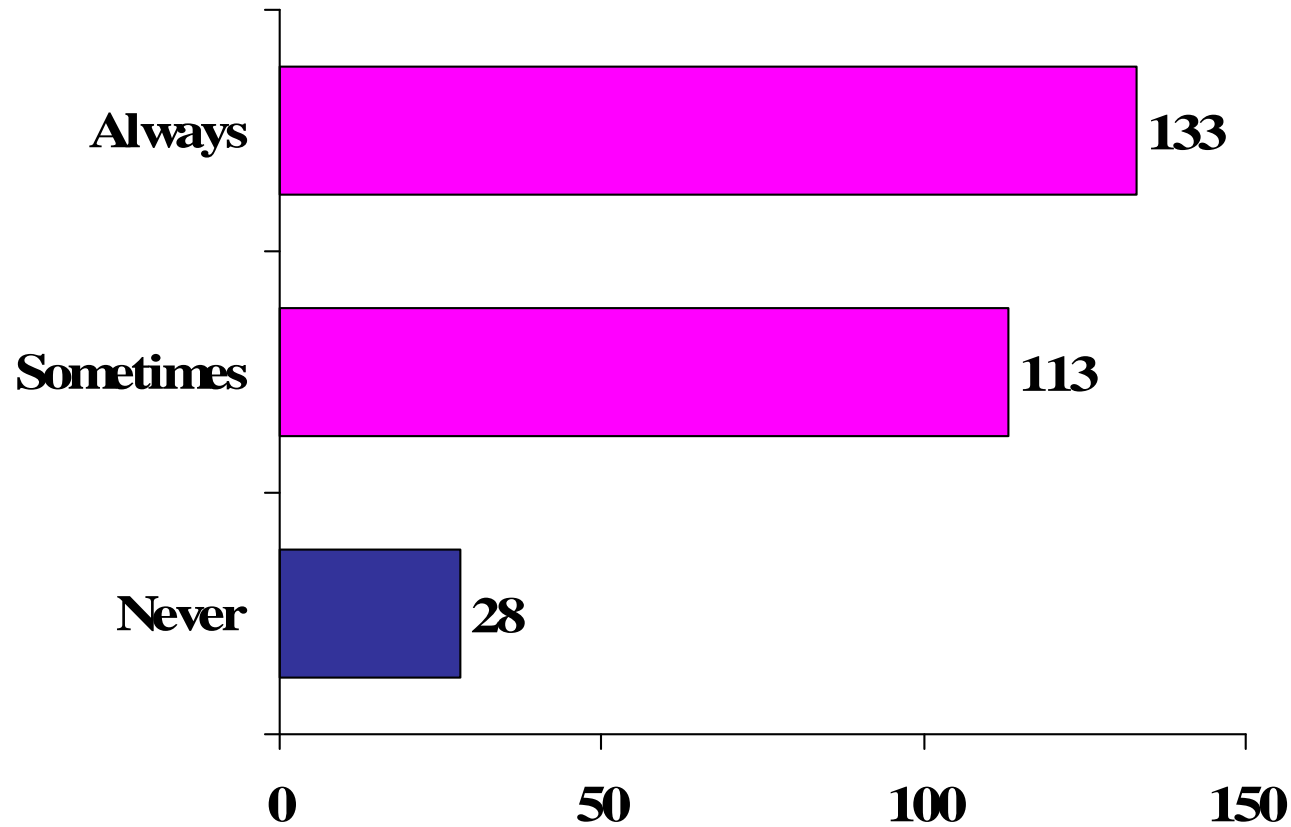


Who Makes Presentations?

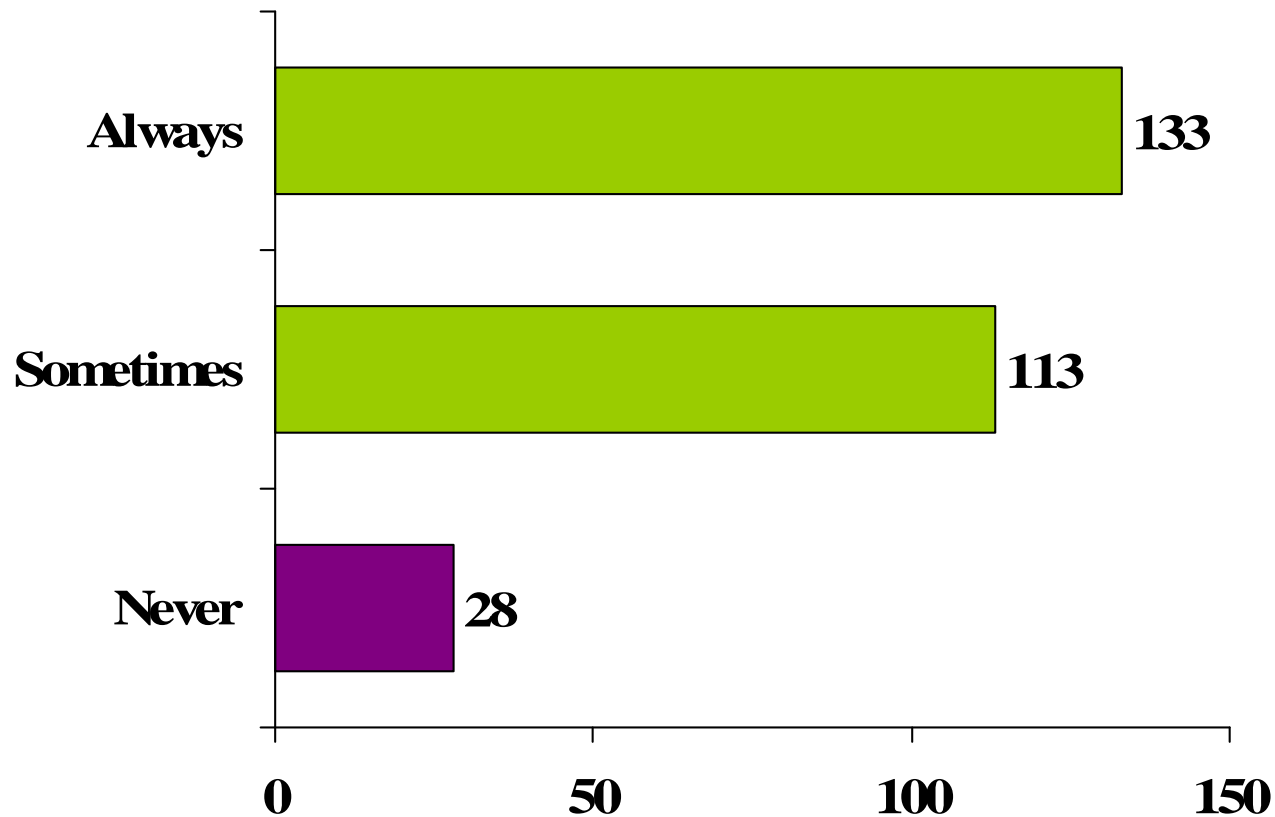
# How often does the quality function make a presentation?



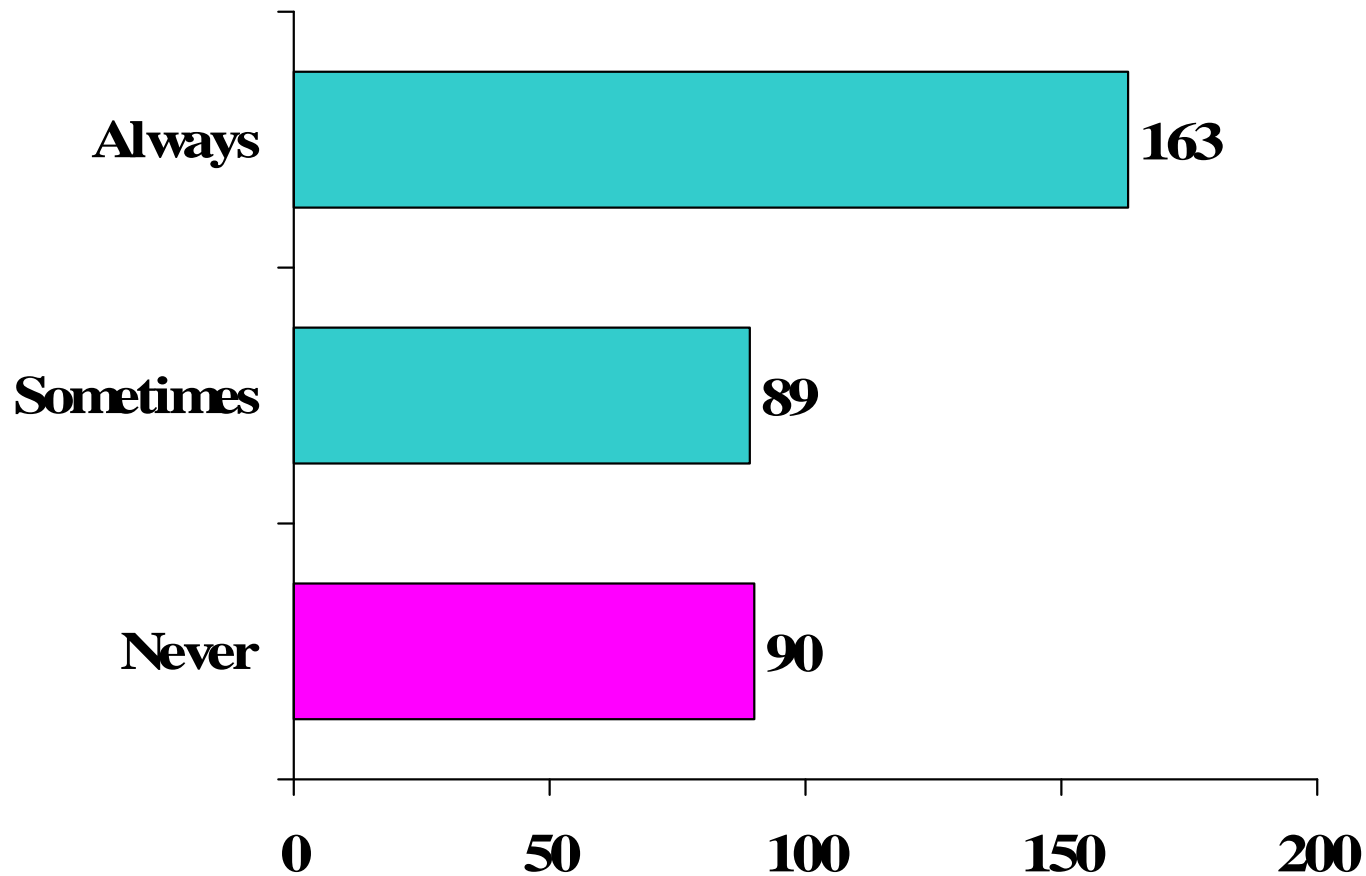
# How often does manufacturing make a presentation?



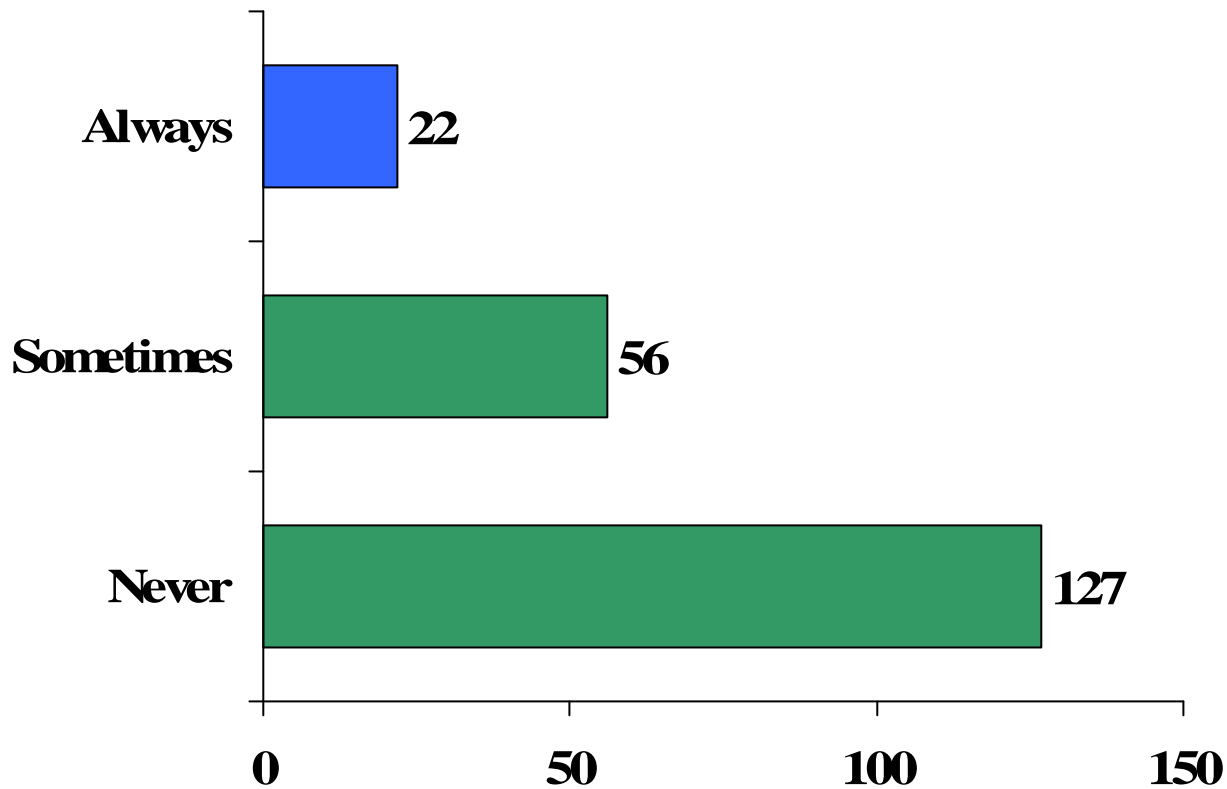
# How often does operations make a presentation?



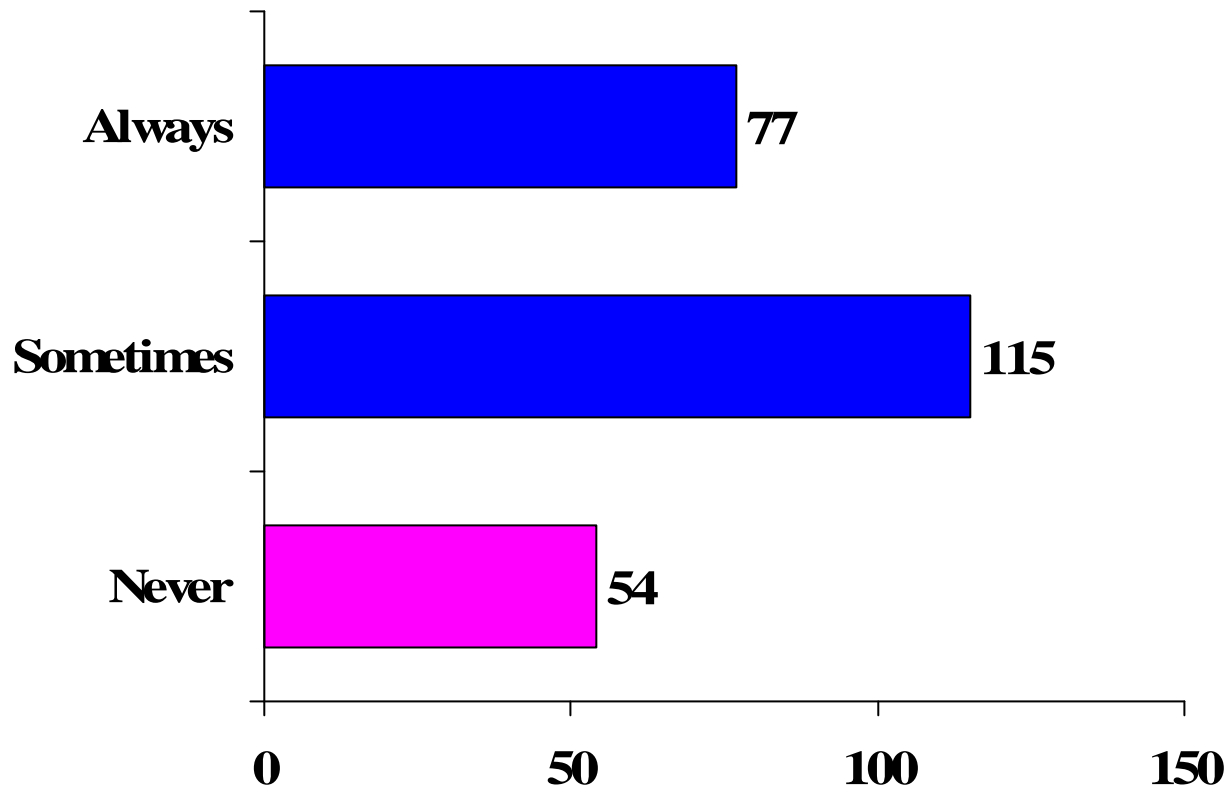
# How often does regulatory affairs make a presentation?



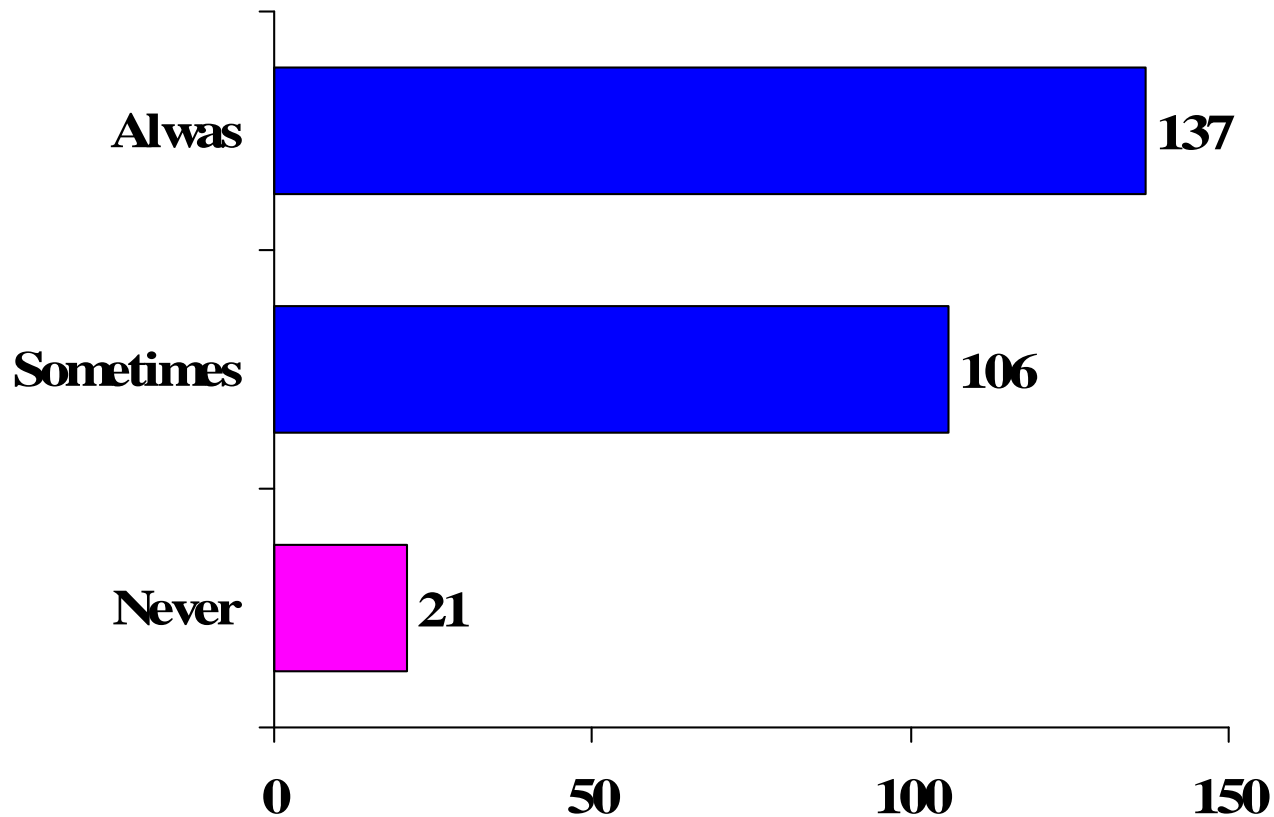
# How often does the president make a presentation?



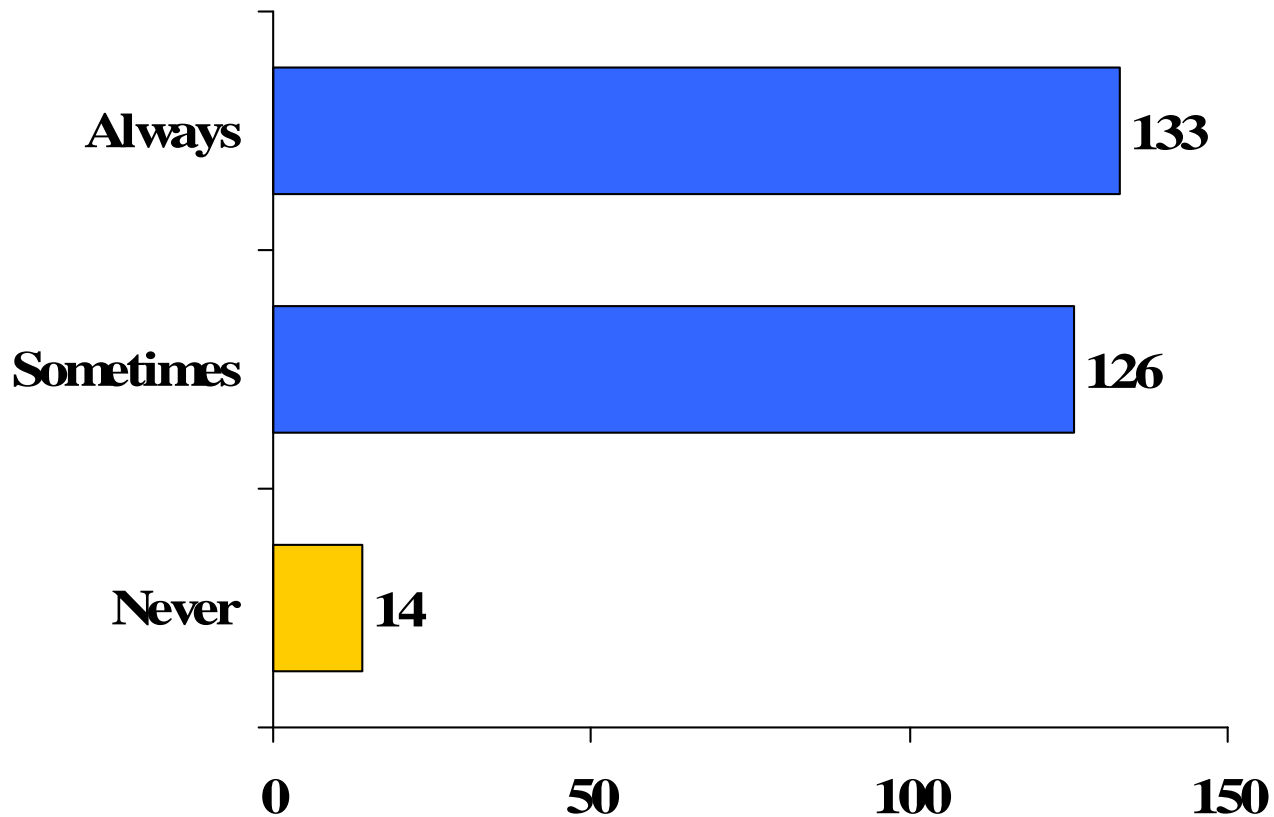
# How often do vice presidents make a presentation?



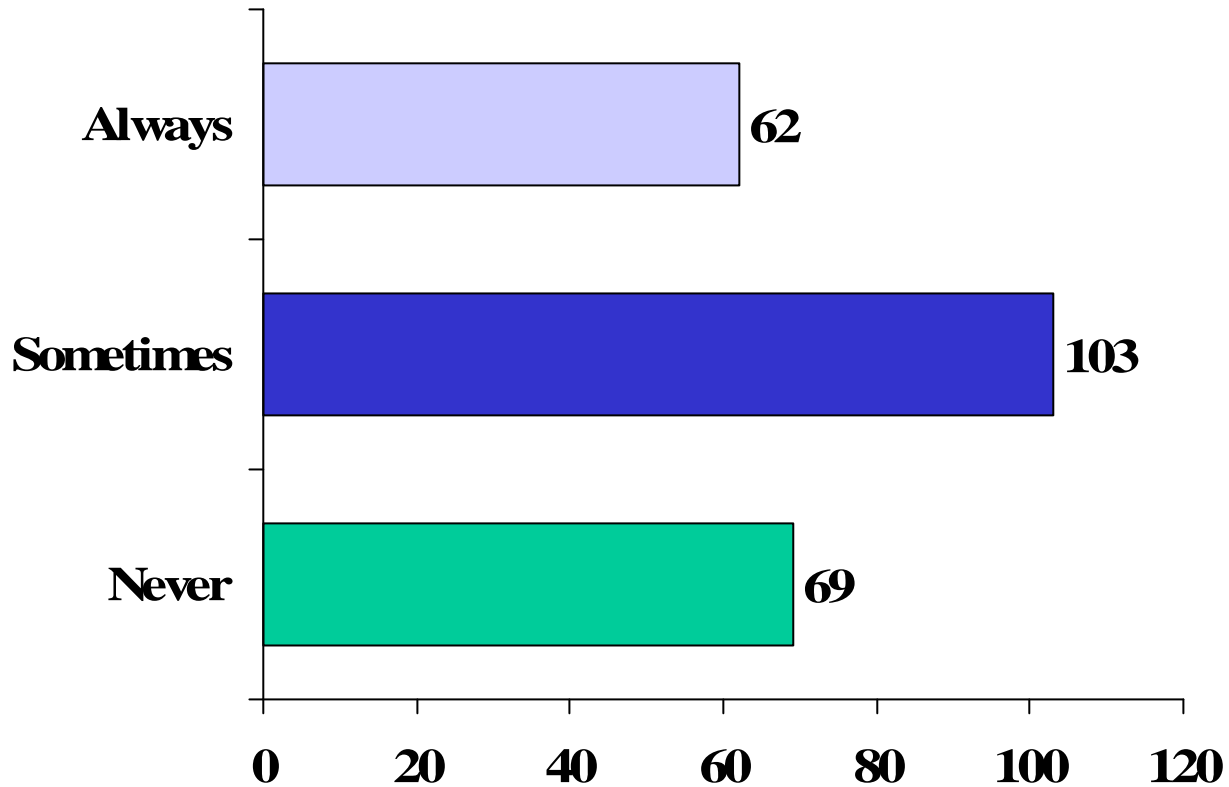
# How often do directors make a presentation?



# How often do managers make a presentation?

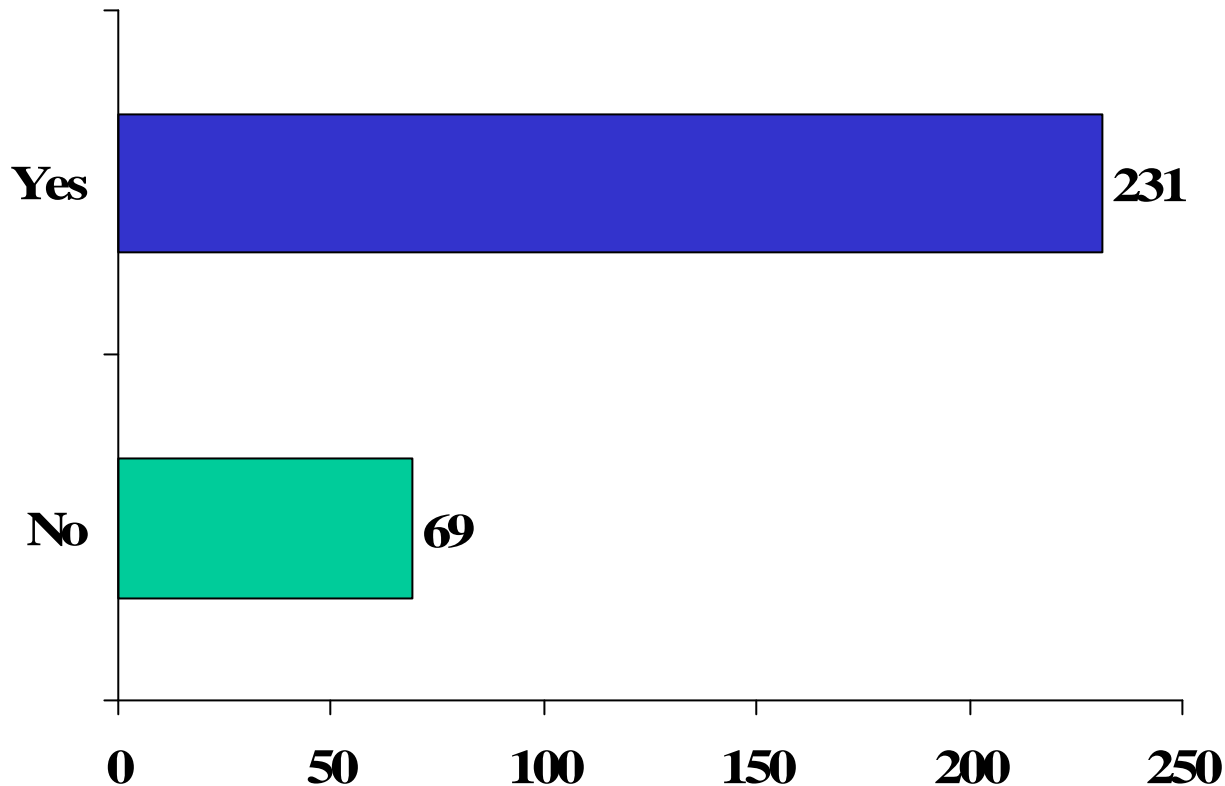


# How often do staff level people make a presentation?

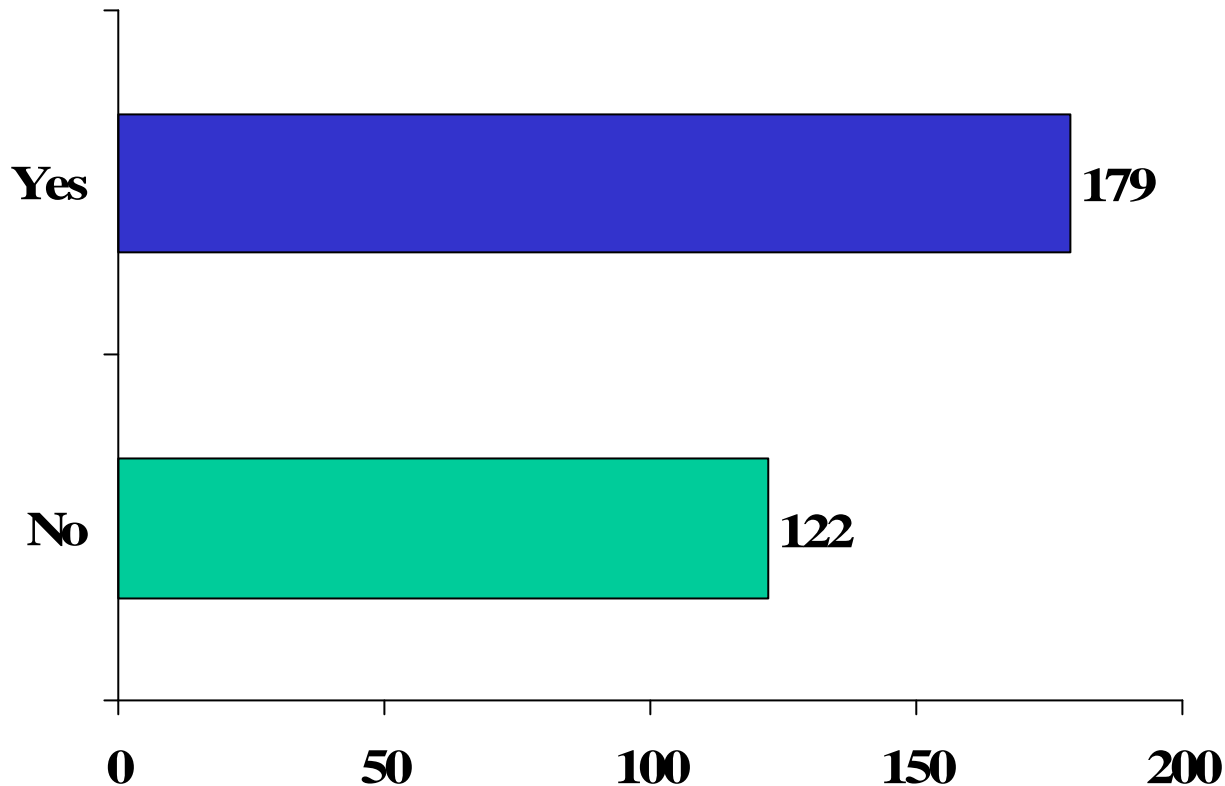


What Items Are Addressed  
During Reviews and What Are  
the Results?

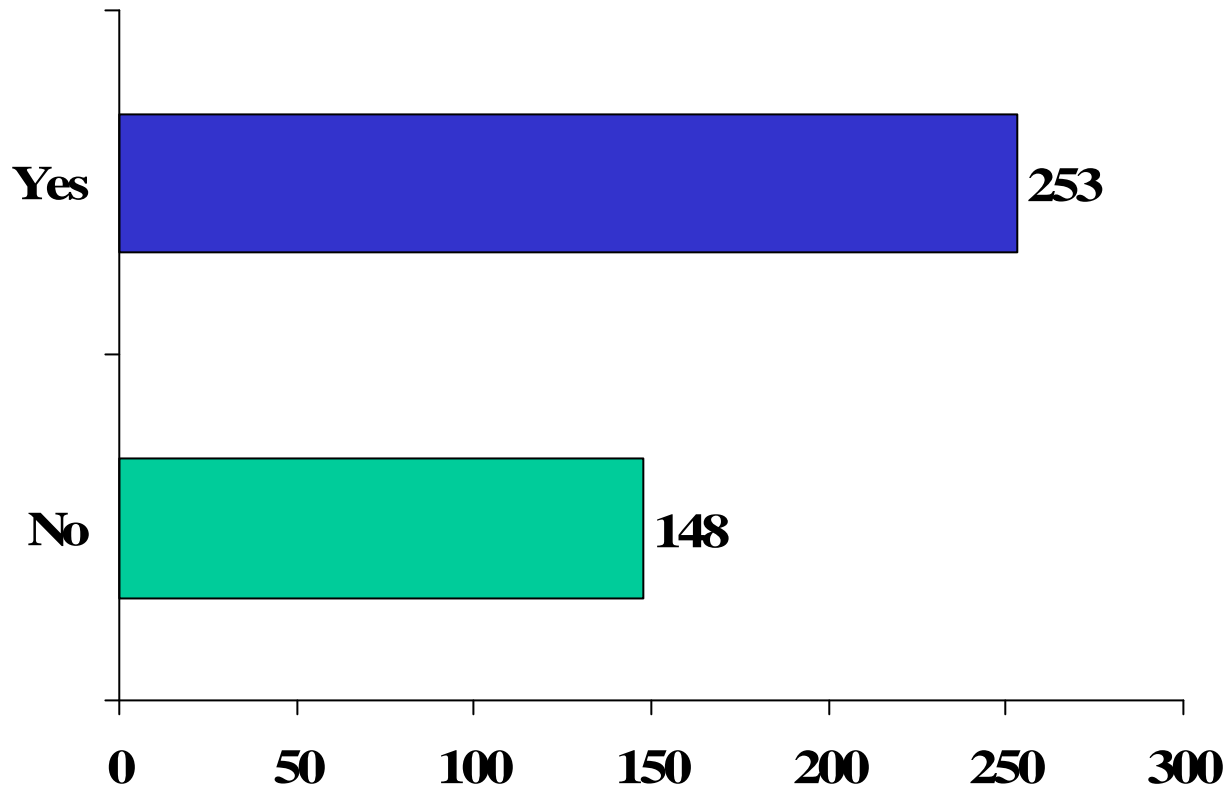
# Does management ask if the firm has the appropriate resources?



# Does management ask if the staff have the appropriate skill sets?



# Does management ask if there are any new regulatory requirements?



# Are actions taken as a result of management reviews?

- Yes - 180 firms
- No - 120 firms
  - 10 firms provided details
  - 110 firms didn't answer the question

# Positive Actions Firms Have Taken As a Result of Review

- Re-evaluated quality objectives for the year
- Implemented new quality policy that reflects business objectives
- Establish multifunctional CAPA teams
  - Action is assigned to responsible area
  - Time frames provided for follow-up
- Reprioritization of compliance issues
- Re-audit problems which ensures accountability

# Positive Actions (continued)

Provided additional resources

- Staff
- New initiatives such as technology (complaint database, paperless documentation system)
- Product improvement initiatives
- Sharing inspection results among divisions
- Obtaining new suppliers
- Eliminate root cause for MDRs
- Training
- 3<sup>rd</sup> party to conduct audit

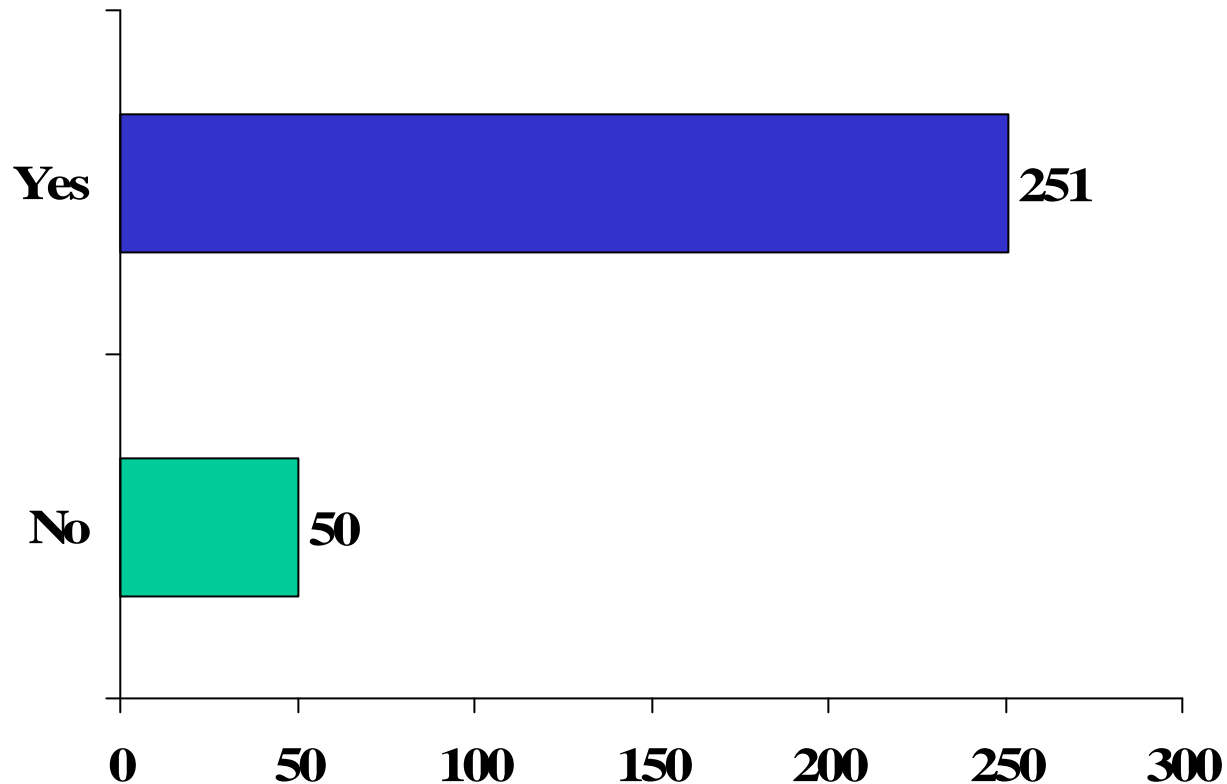
# Positive Actions (continued)

- Changes to quality manual, SOPs, staffing
- Reorganization of QA function
- Evaluate existing talent

# Lack of Action

- None
- Very little
- No specific action, only guidance
- Not sure
- Updates to previous presentations
- Discuss the actions we will take during monthly meetings
- Reallocation of resources (If we want more people, we need to find the funds)

# Does management ask if internal audits are effective?



# How do you measure the effectiveness of internal audits?

- Measure the # of outside audit findings (FDA and notified bodies)
- Trend the # of observations and the timely completion of CAPA
- Examine the # of repeat occurrences
- Look for similarity of findings across business units
- Determine if there is a decreased number of customer complaints and field corrective action

# Effectiveness of Internal Audits (continued)

- Conduct customer surveys on how firm product is perceived compared with the competition
- Compare the #of annual findings and compare that with the number of 483 observations
- Audit the auditor

# Challenges That Were Identified in Conducting Management Reviews

- Scheduling the meeting & having enough time to cover the issues
- Engaging top management
- Making the review about taking action rather than a recap about what has happened
- Preparing the data in a useful format with the right level of detail

# Challenges (continued)

- Limiting the preparation time
- Making the information relevant to the business objectives
- Preventing the meeting from getting side tracked
- Getting buy in from all departments and getting people to follow up

# Innovative Practices

- Provide written materials in advance of the meeting
  - Discuss “hot issues”
  - Allow questions about other issues
- Have a list of standing topics and present different topics at each meeting
- Use visual aids; bring in products or pictures of products
- Summarize each chart or report and explain how it relates to the business

# Innovative Practices (continued)

- Have a tiered approach; have levels of reviews and present most important data to top management
- Ask executive management to make the presentation
- Give junior people an opportunity to present information
- Focus a lot of the review on new products
- Make top management aware of the absence of key executives

# Innovative Practices (continued)

- Use Trackwise to track follow up action
- Send input and output to all nonexempt employees
- Serve lunch at the end of the review