

Globally Harmonized Quality System Survey*

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Tara Kambeitz, Underwriters Laboratories*

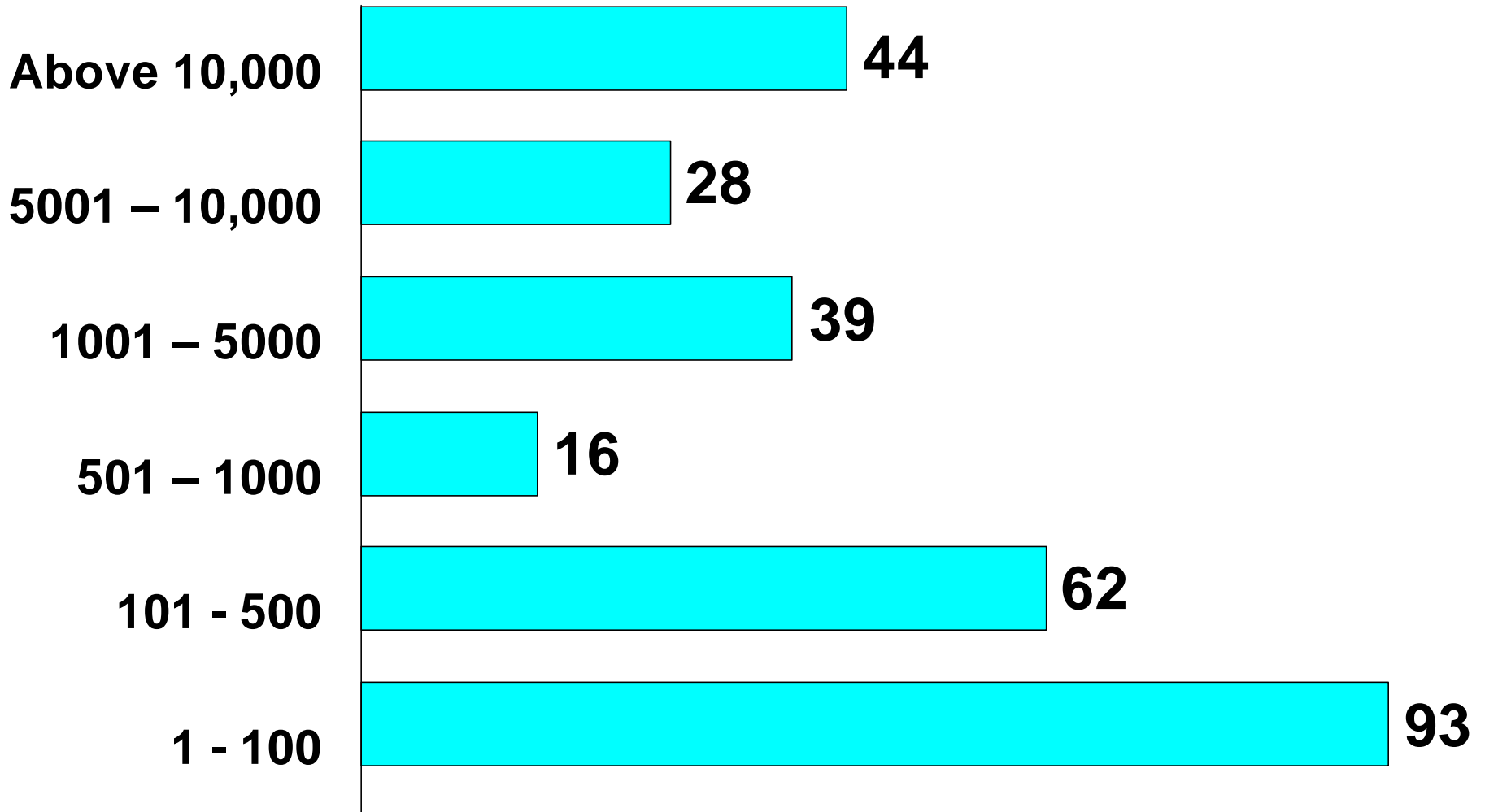
Demographics

- Survey conducted October 2008
- 283 Respondents (represented by # on chart)
- Large, medium and small firms were represented

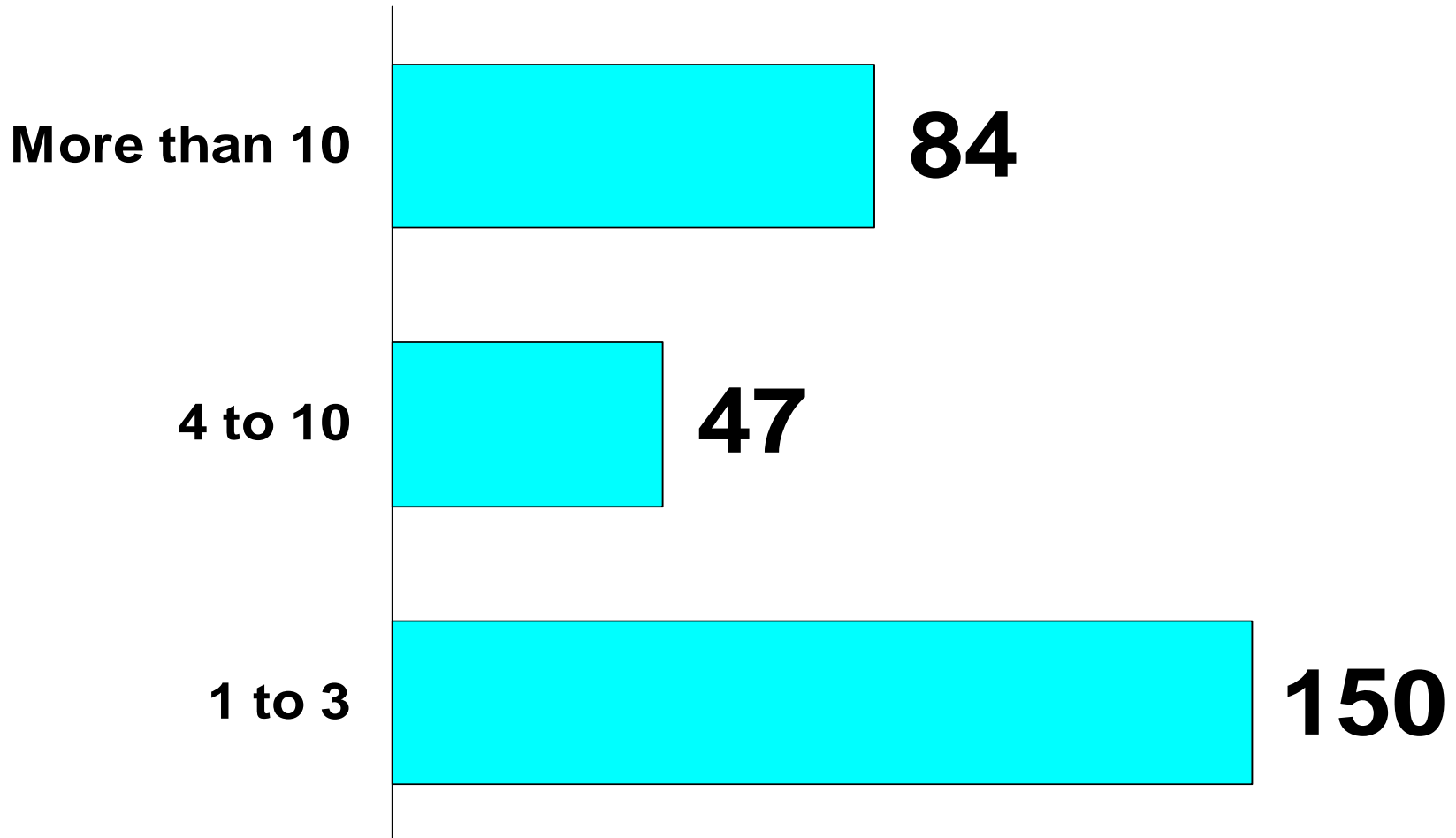
Color Legend



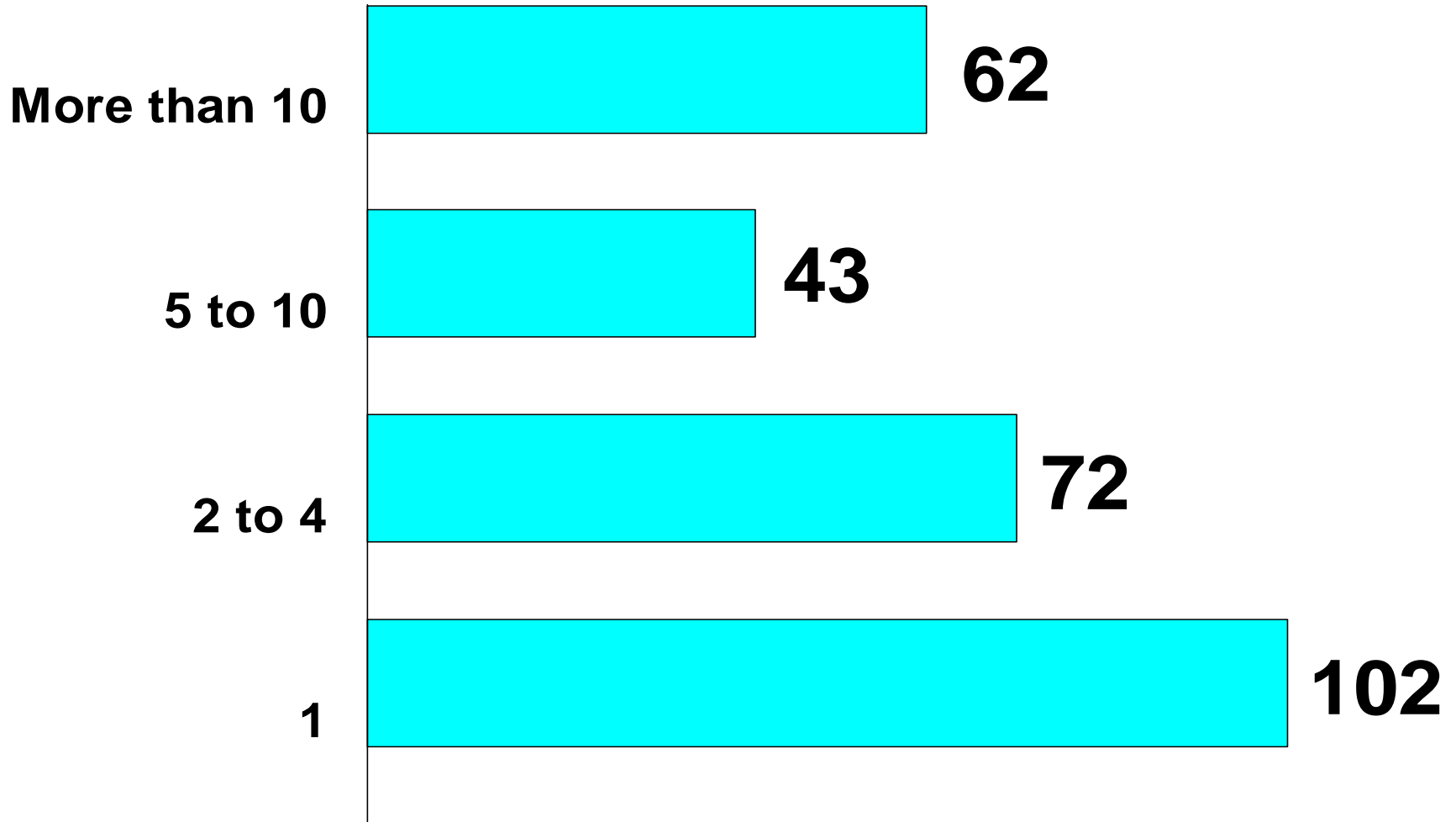
What is the approximate number of employees in your firm?



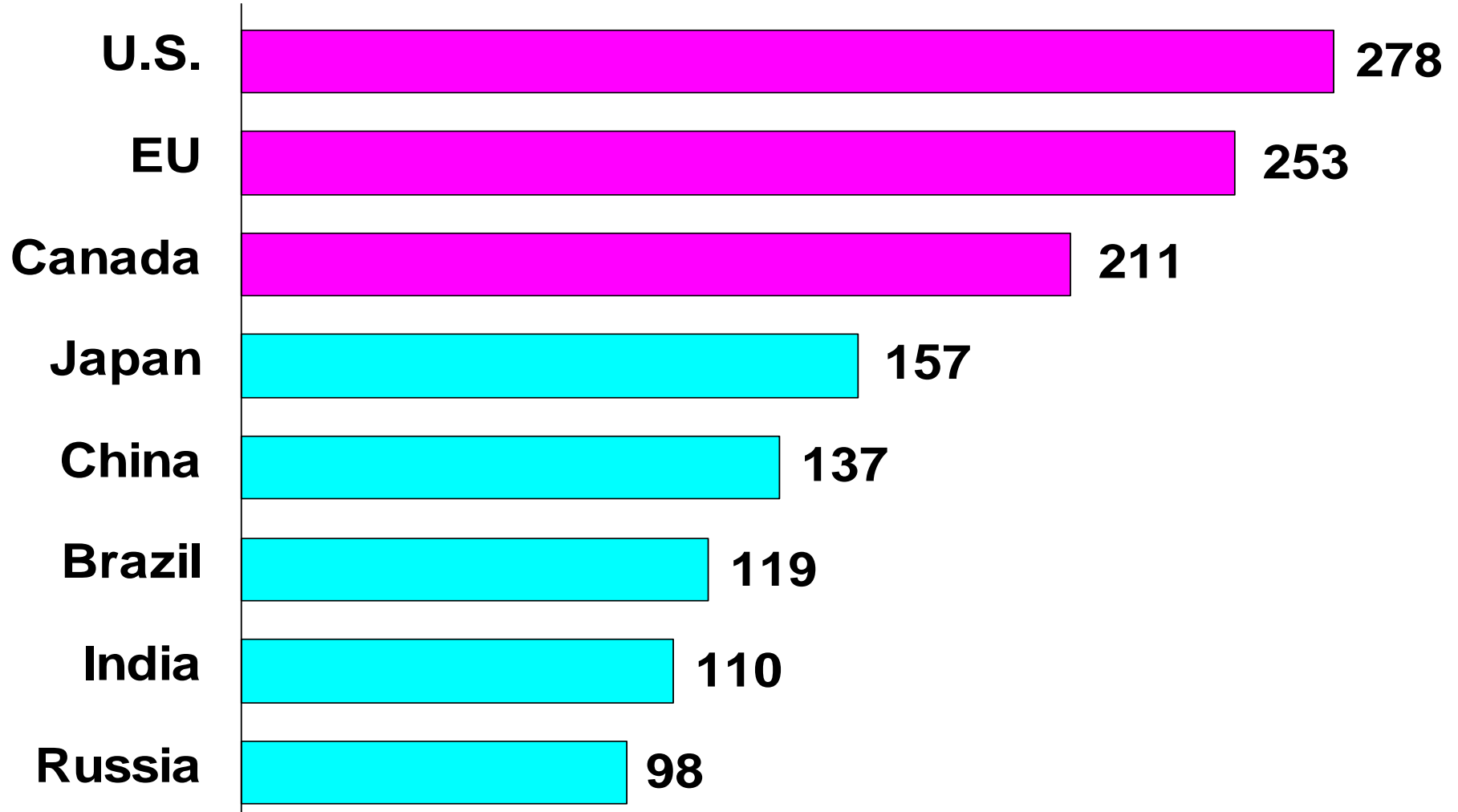
How many sites does your firm have worldwide?



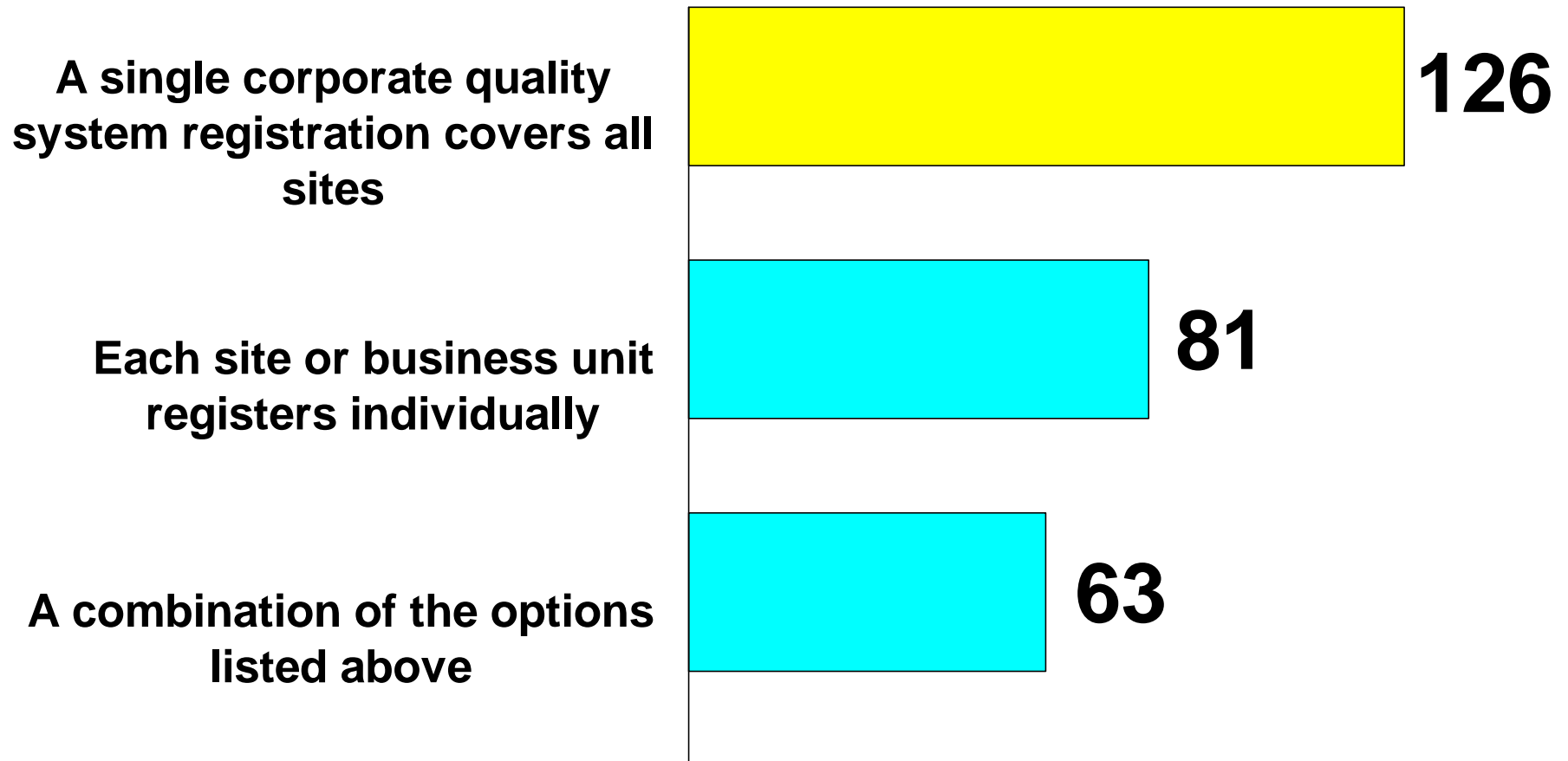
Your firm has facilities in how many countries?



With which countries' regulatory requirements are you obligated to comply? (Check all that apply)

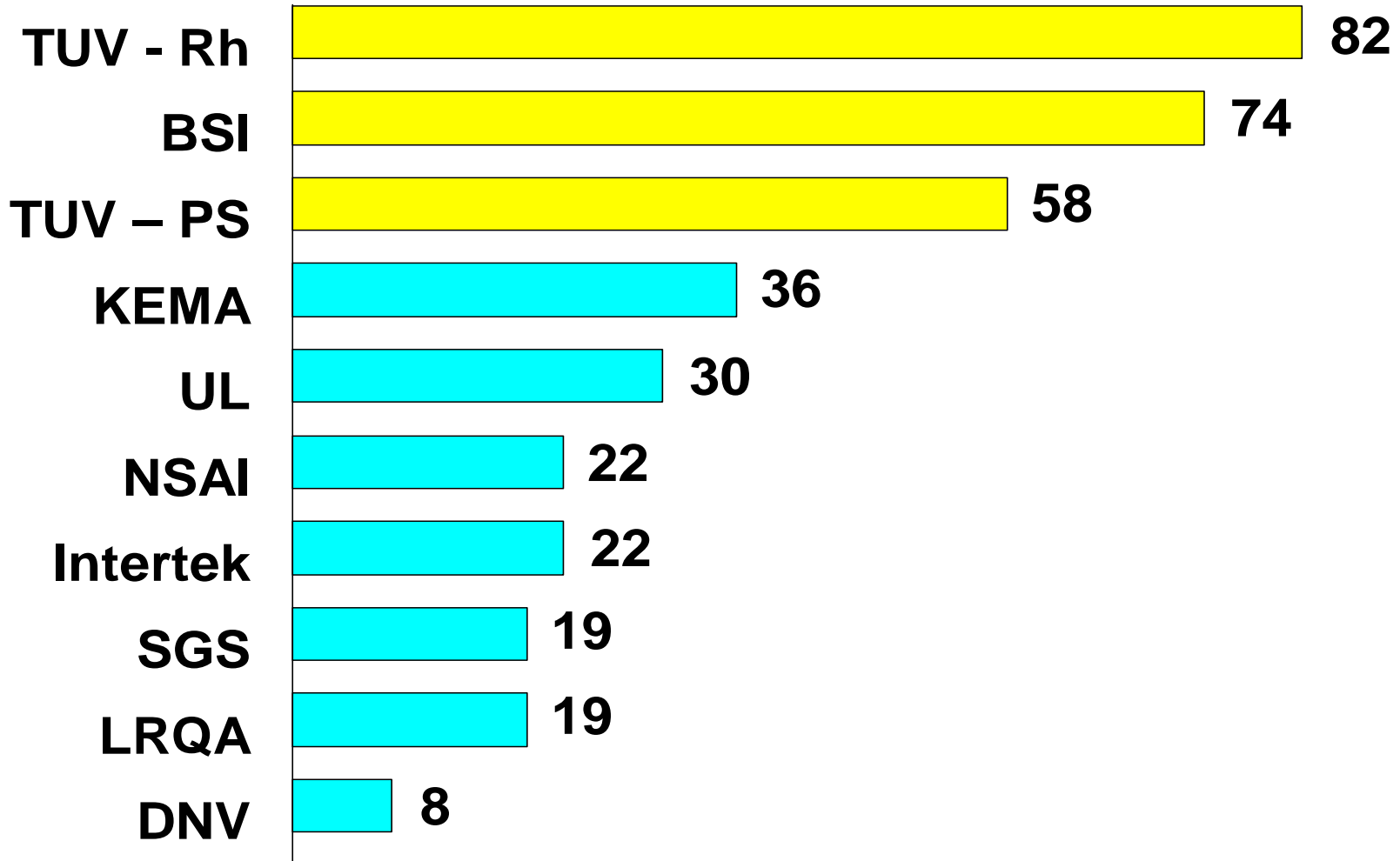


How does your company handle ISO 13485 quality system registrations?

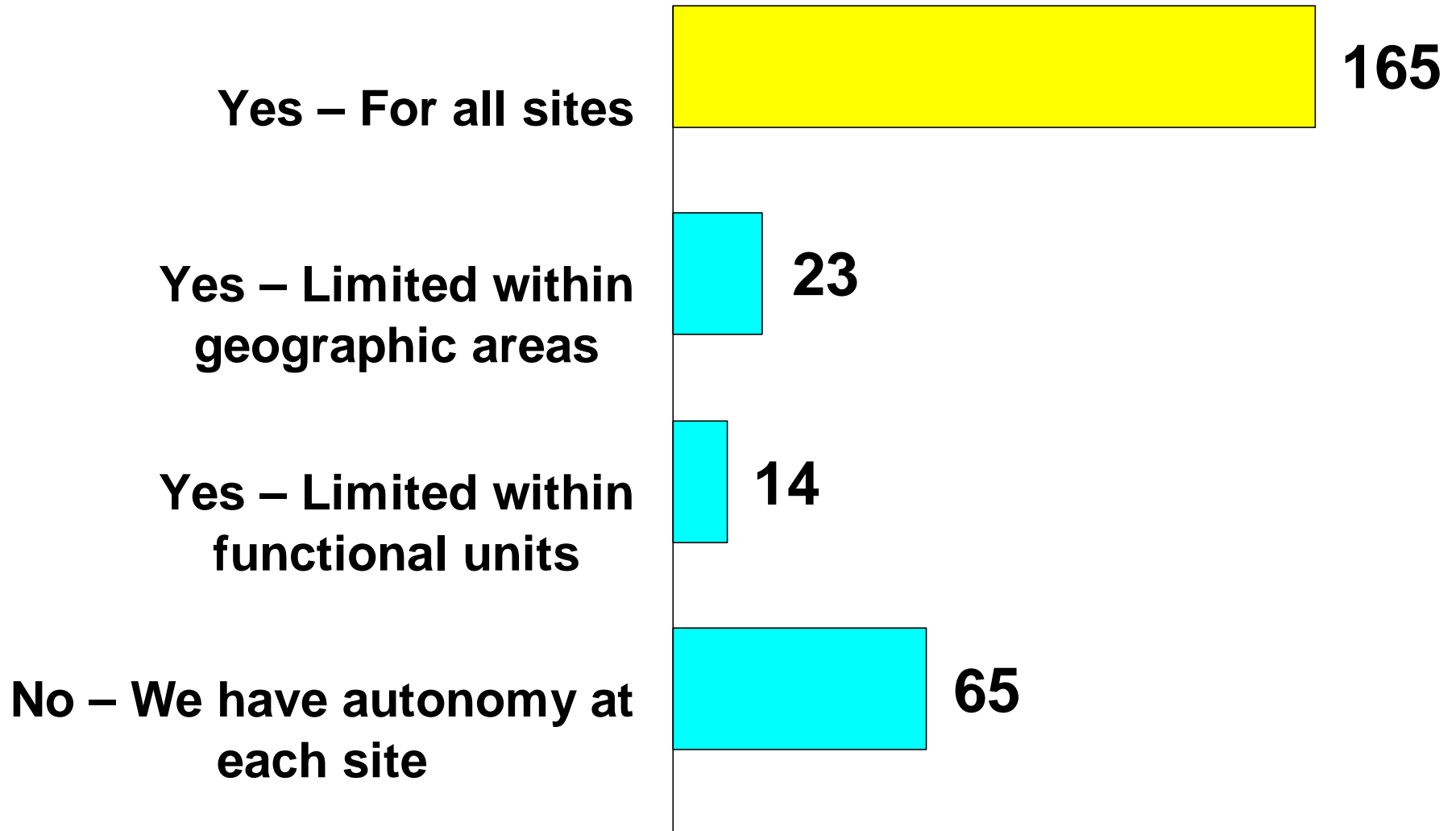


Which notified body/bodies do you use as your Quality System Registrar(s)?

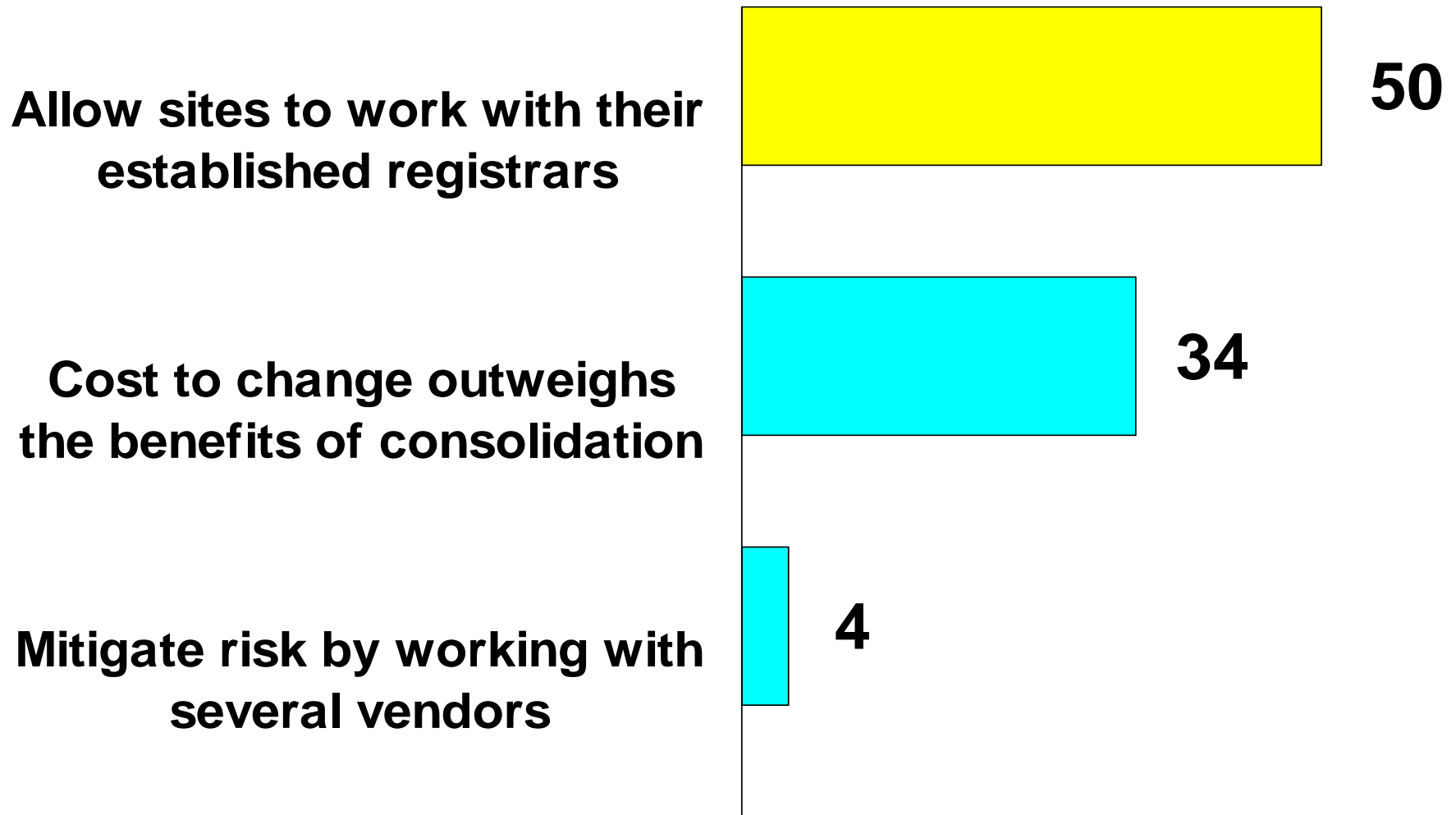
(Check all that apply)



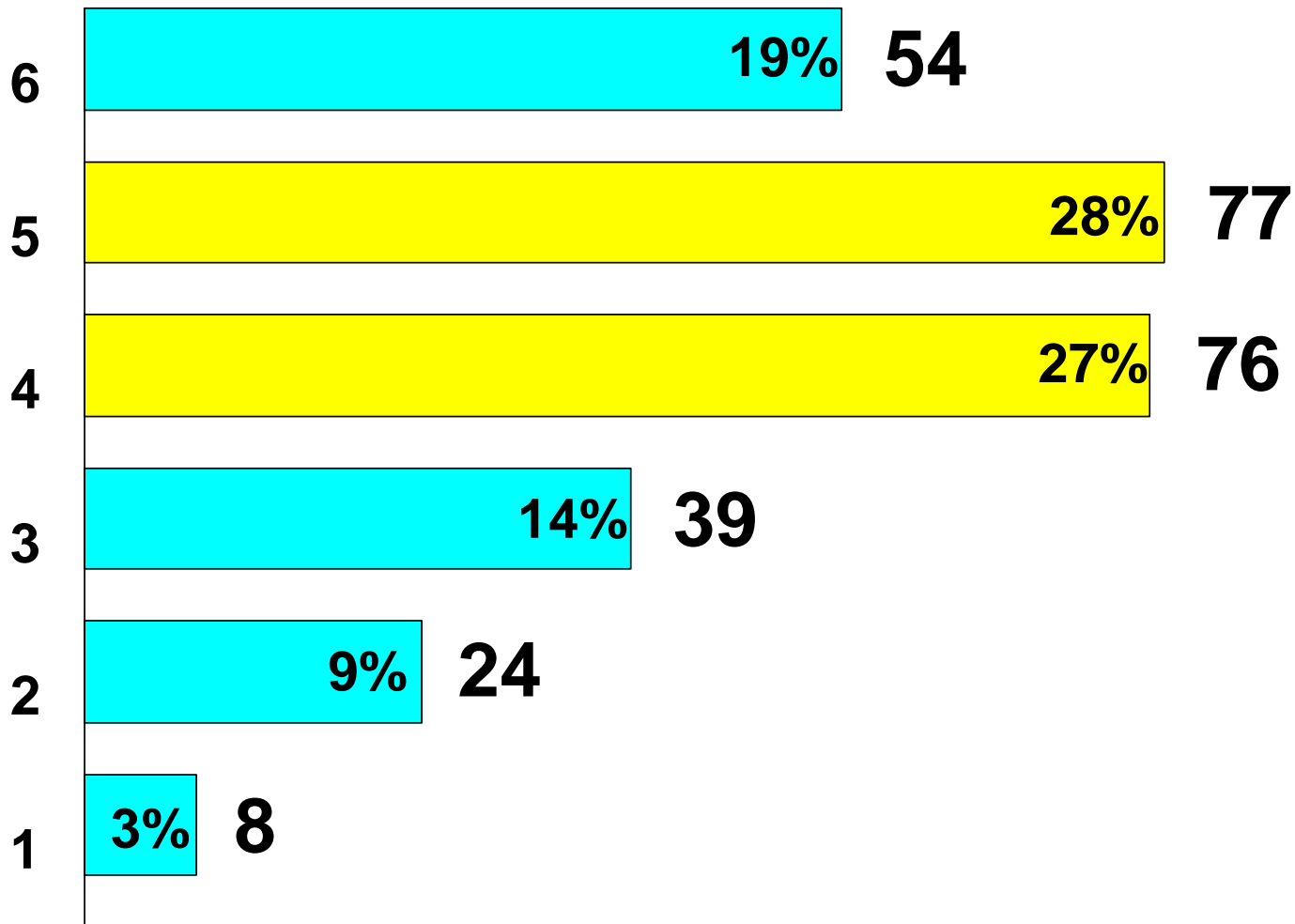
Is your company moving to work with a single Quality System Registrar?



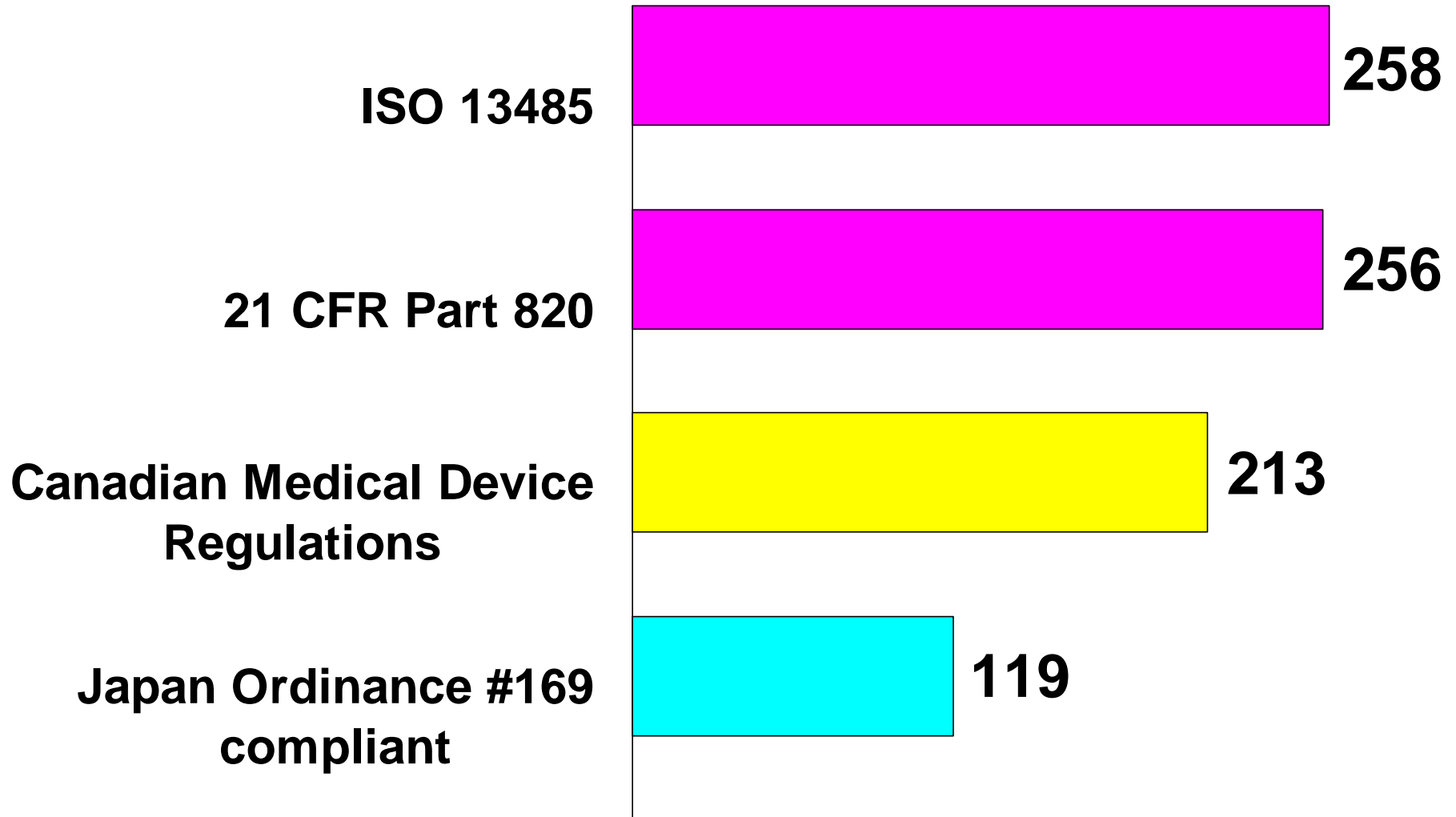
What is the primary reason you have not consolidated your Quality System Registrar among all sites?



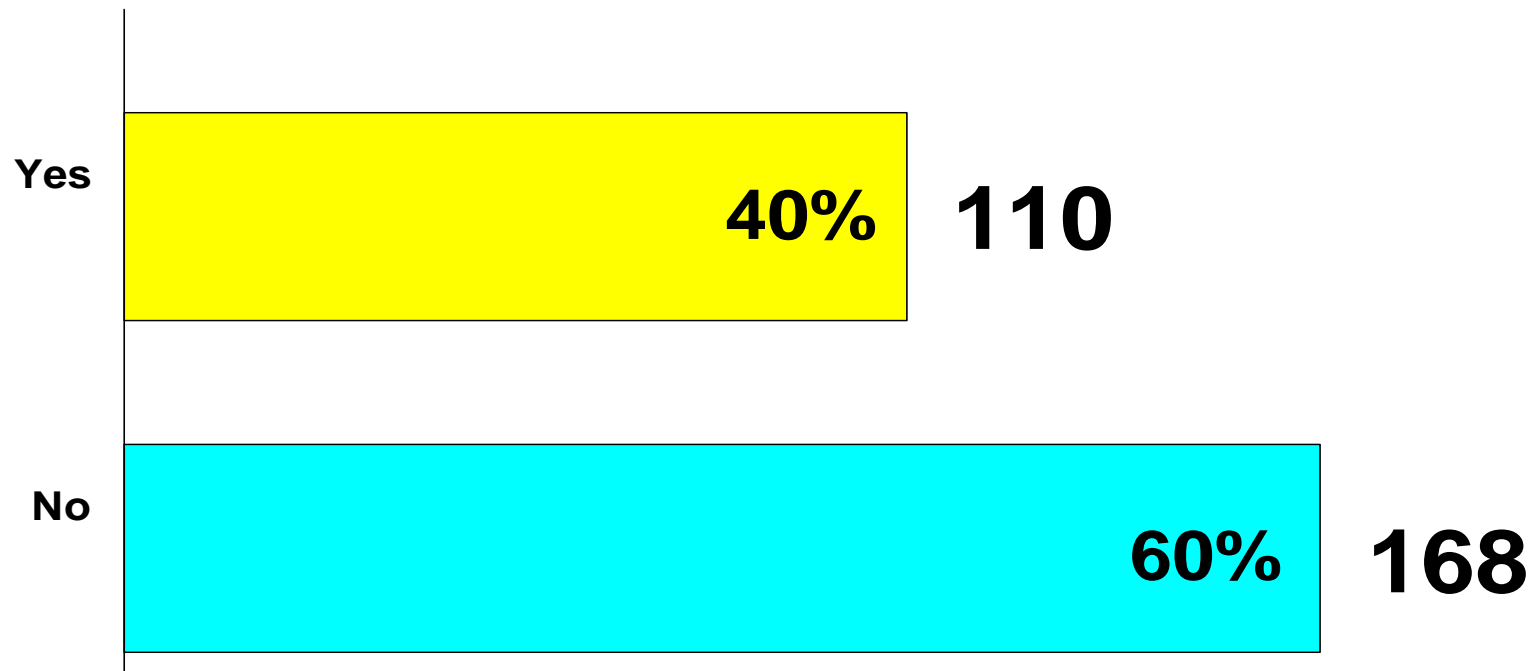
On a scale of 1 – 6, with 6 being the most effective, how effective is your firm in maintaining a globally harmonized quality system?



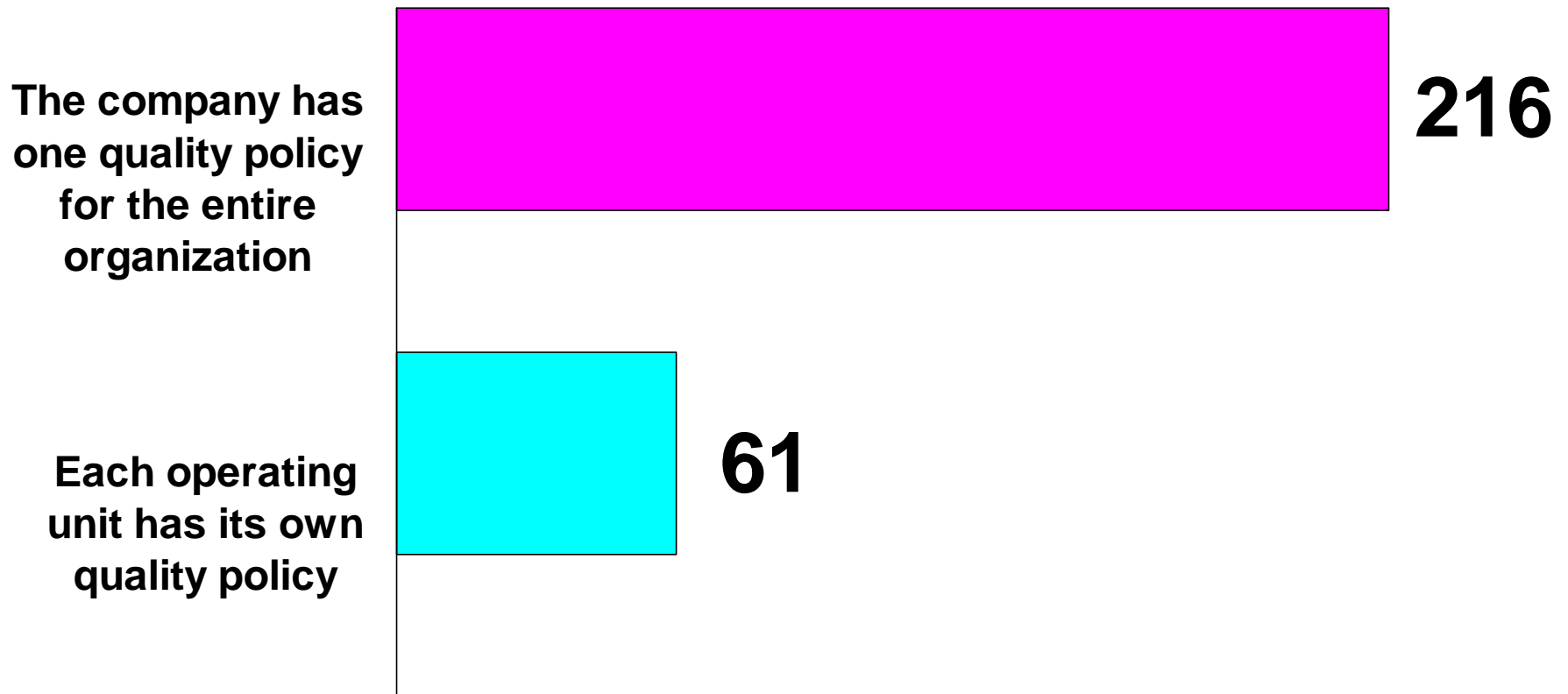
With which requirements does your company comply? (Check all that apply)



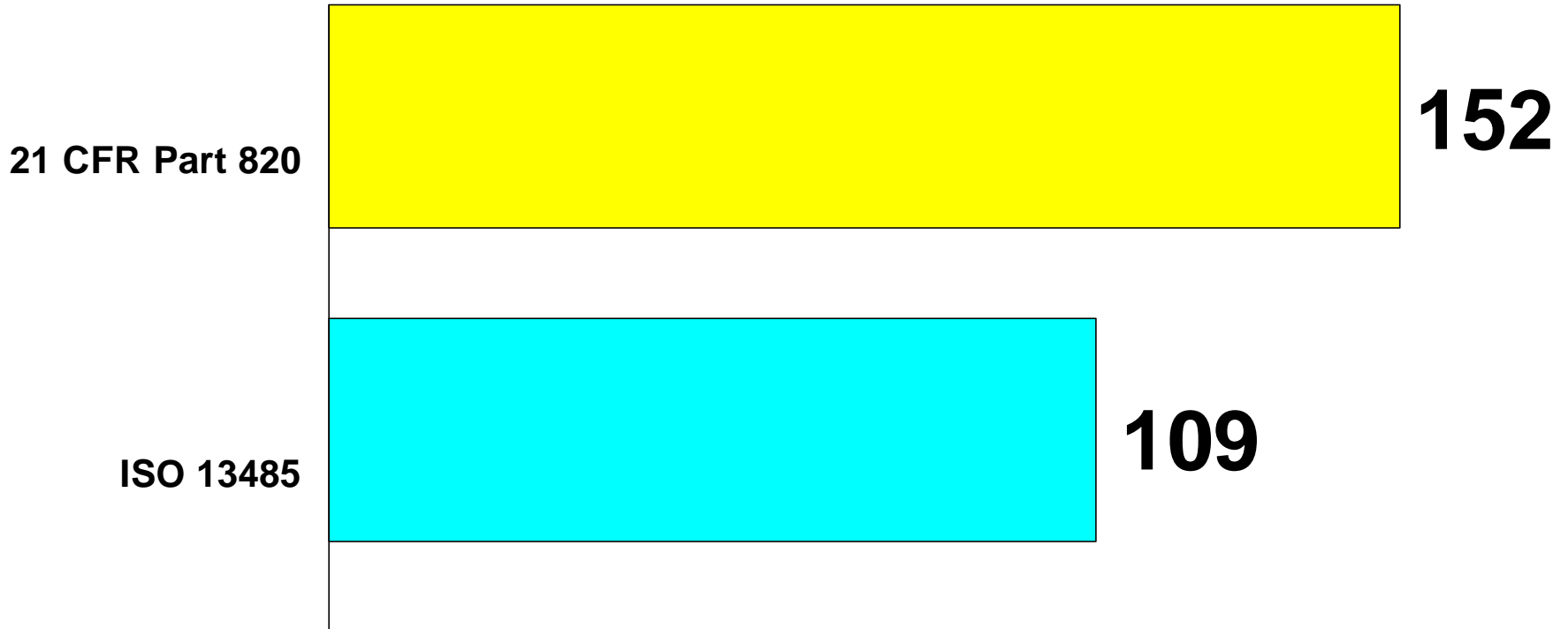
Does your firm have an entity such as a
“Global Quality Council” that meets
regularly and provides general direction for
quality within your organization?



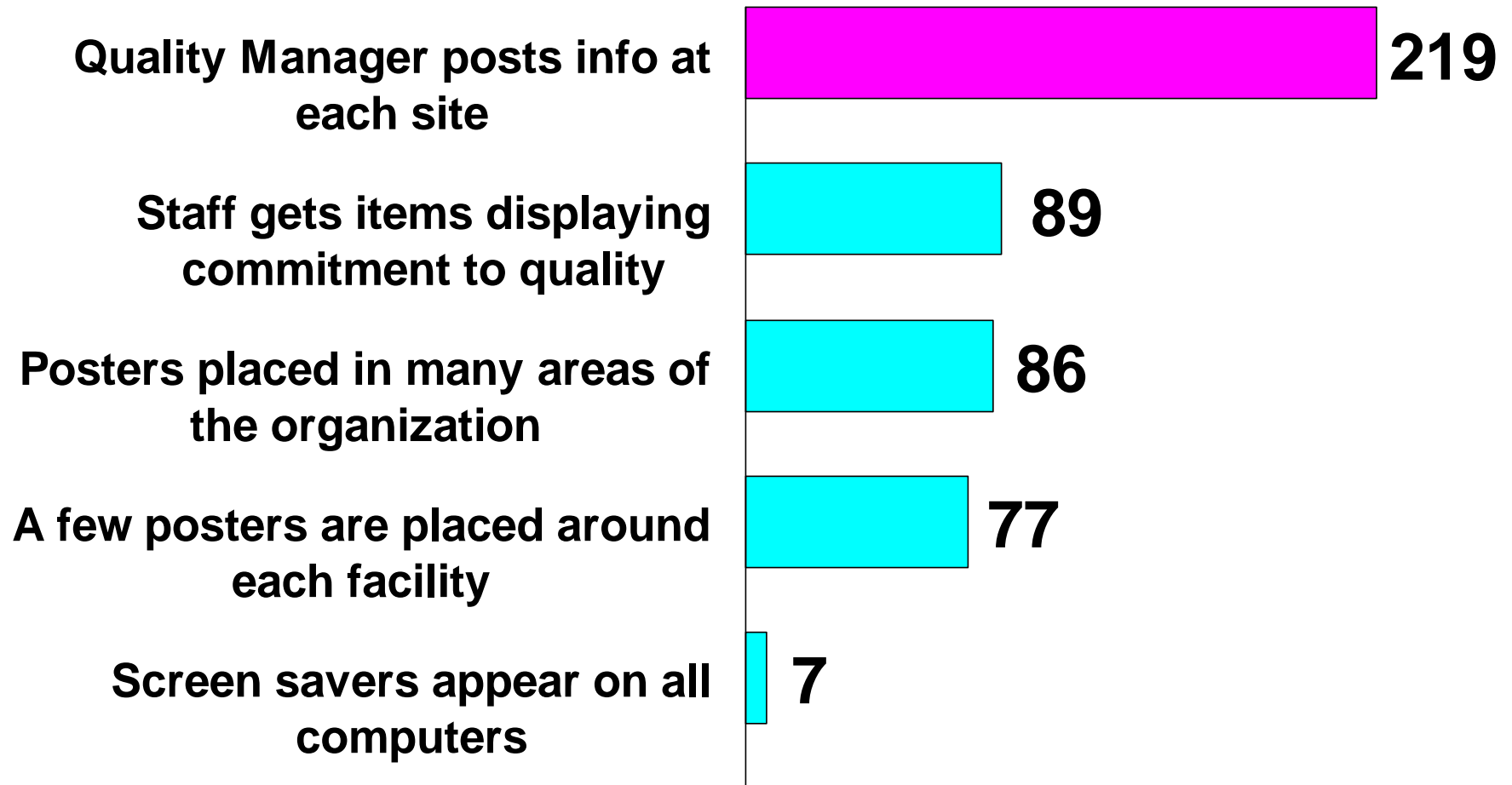
How does your firm structure your quality policy?



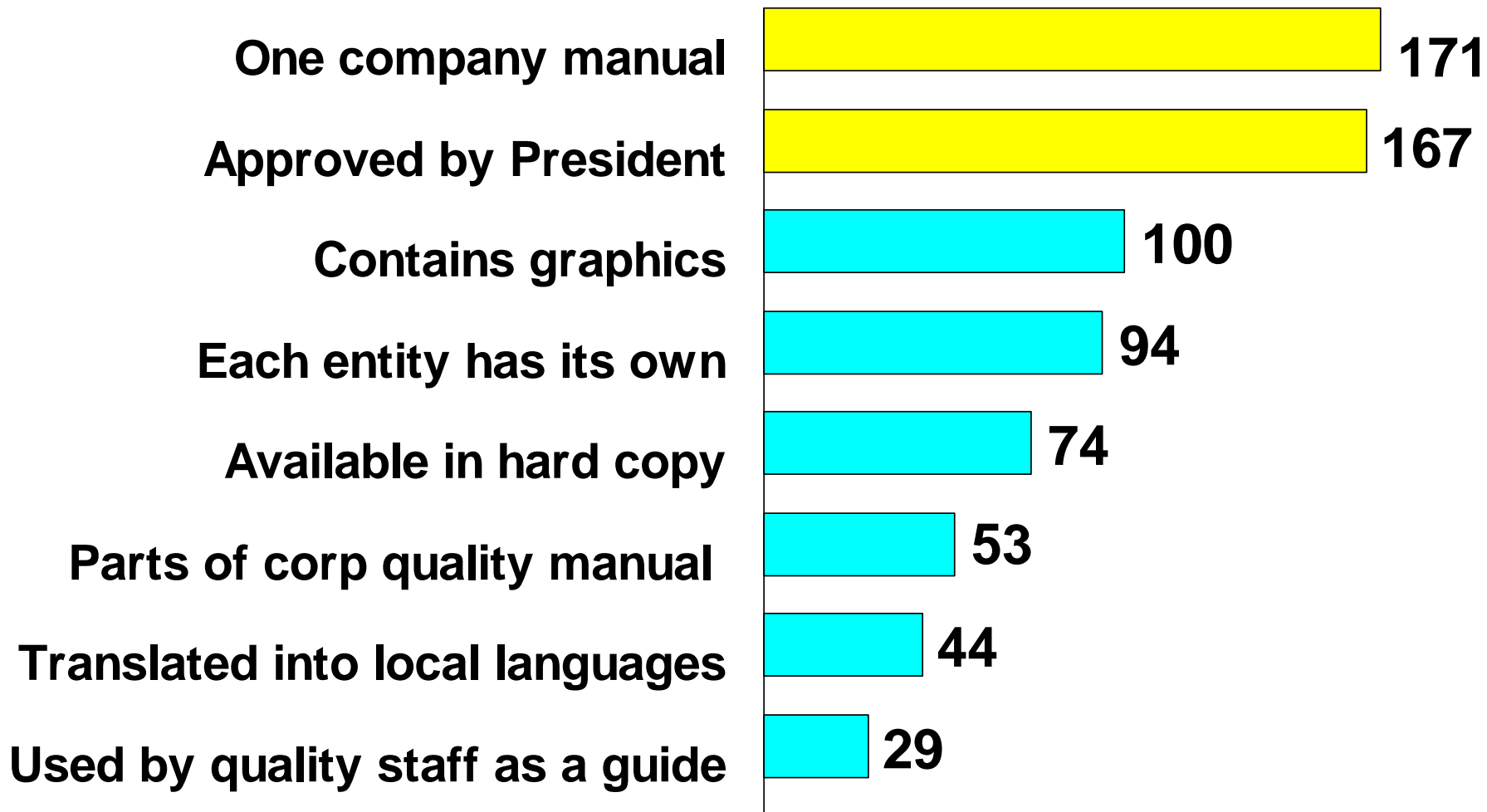
Which of the following served as the starting point for building your Quality System?



How does your firm communicate the importance of quality? (Check all that apply)



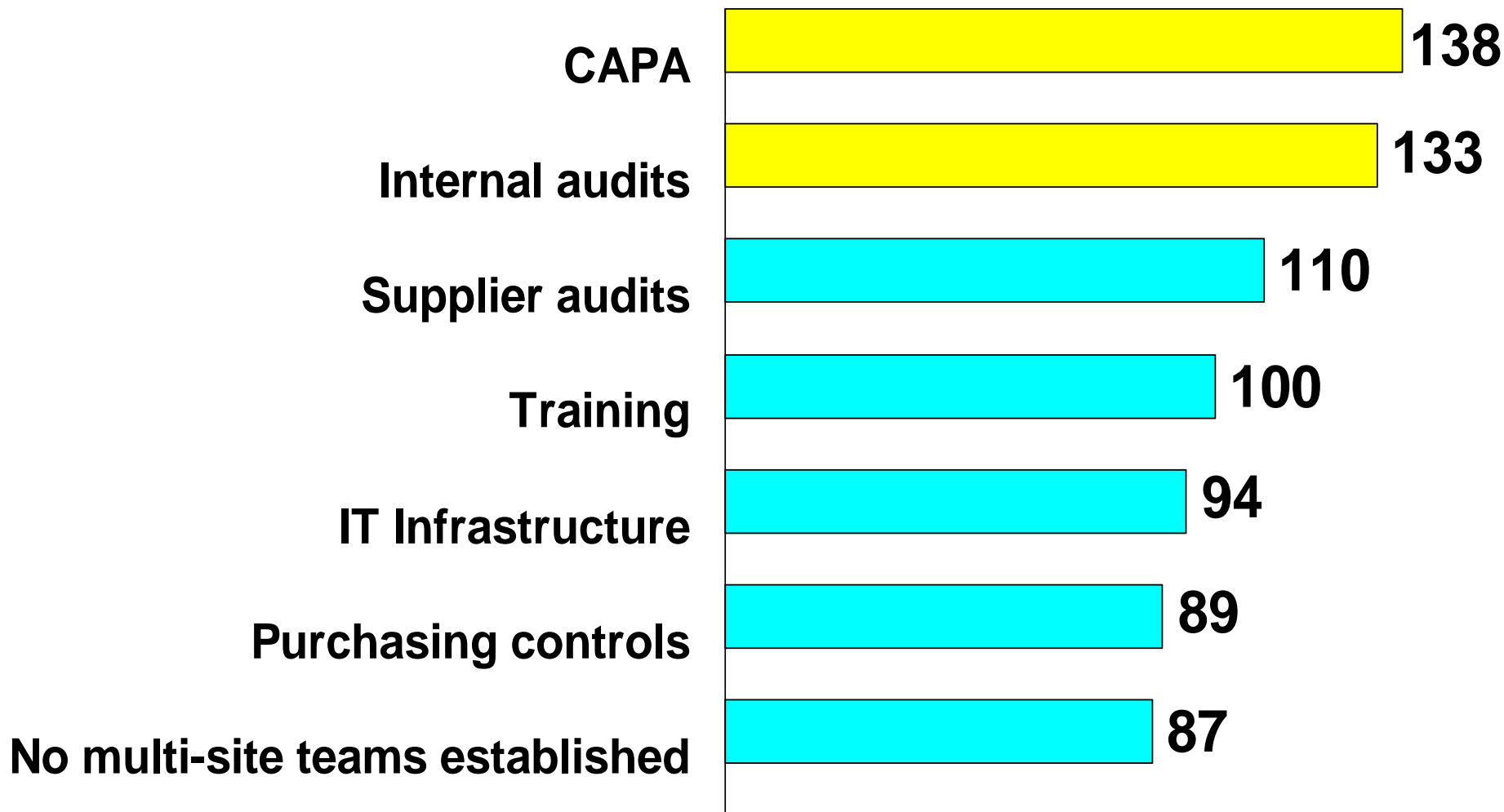
Indicate which of the following relates to your quality manual. (Check all that apply)



If you were inspected by the FDA in the last 2 years, which of the following statements are true?



Which quality system processes are guided by multi-site teams that communicate on a regular basis within your company? (Check all that apply)



For which areas do you collect data and share metrics across your organization?

(Check all that apply)

