TEAM-PRRC

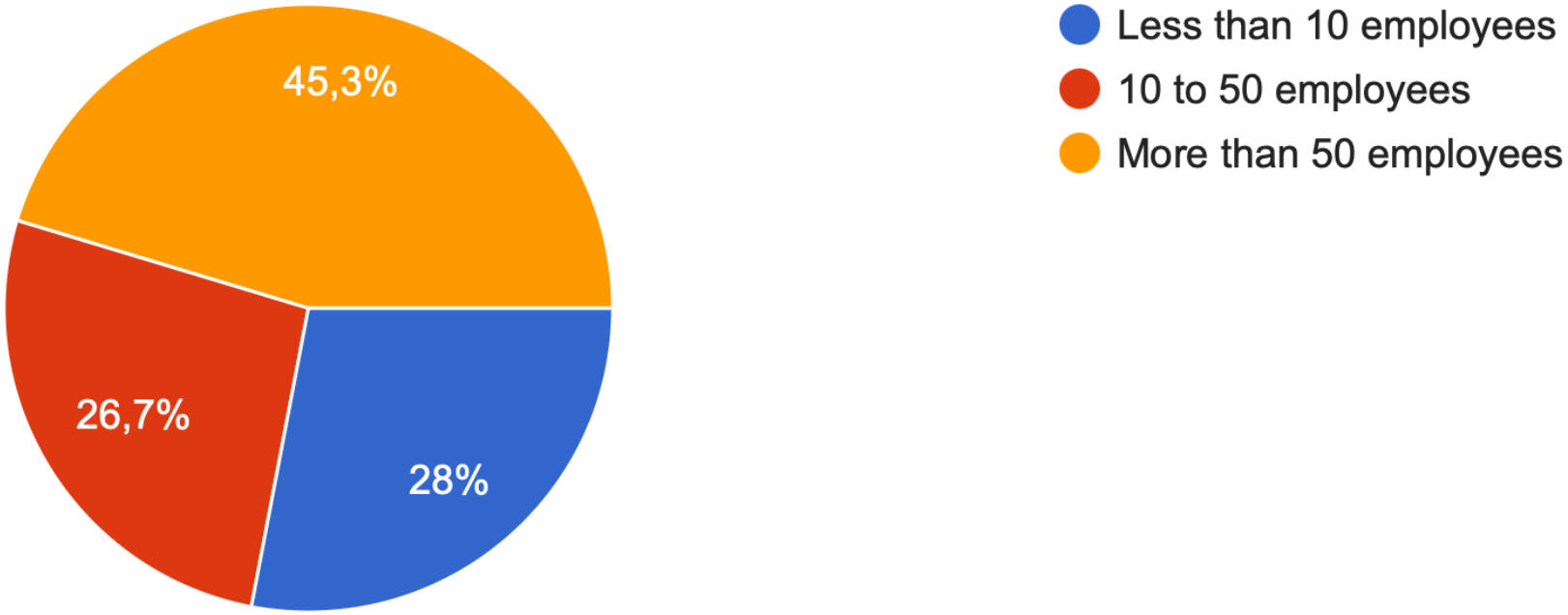
“Compliant together”

RESULTS OF THE SURVEY (SEPT/OCT 2024)

RESULTS OF THE SURVEY CONDUCTED ABOUT THE PRRC → 150 answers

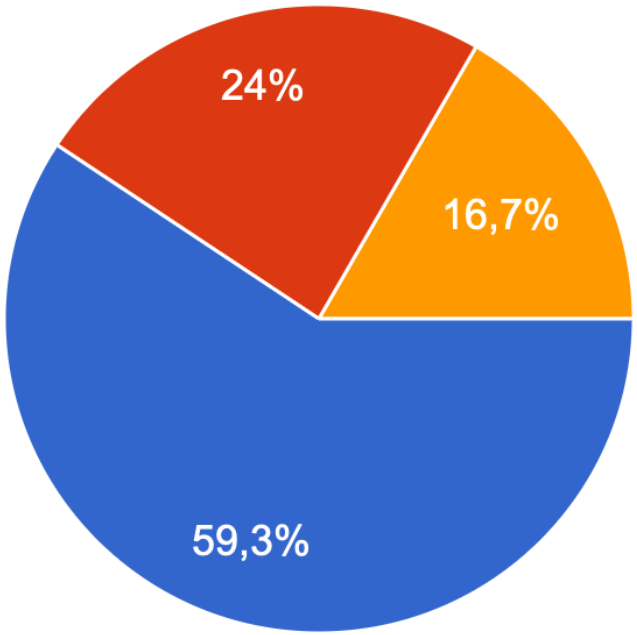
1. To know you better: What is the size of your company?

150 réponses



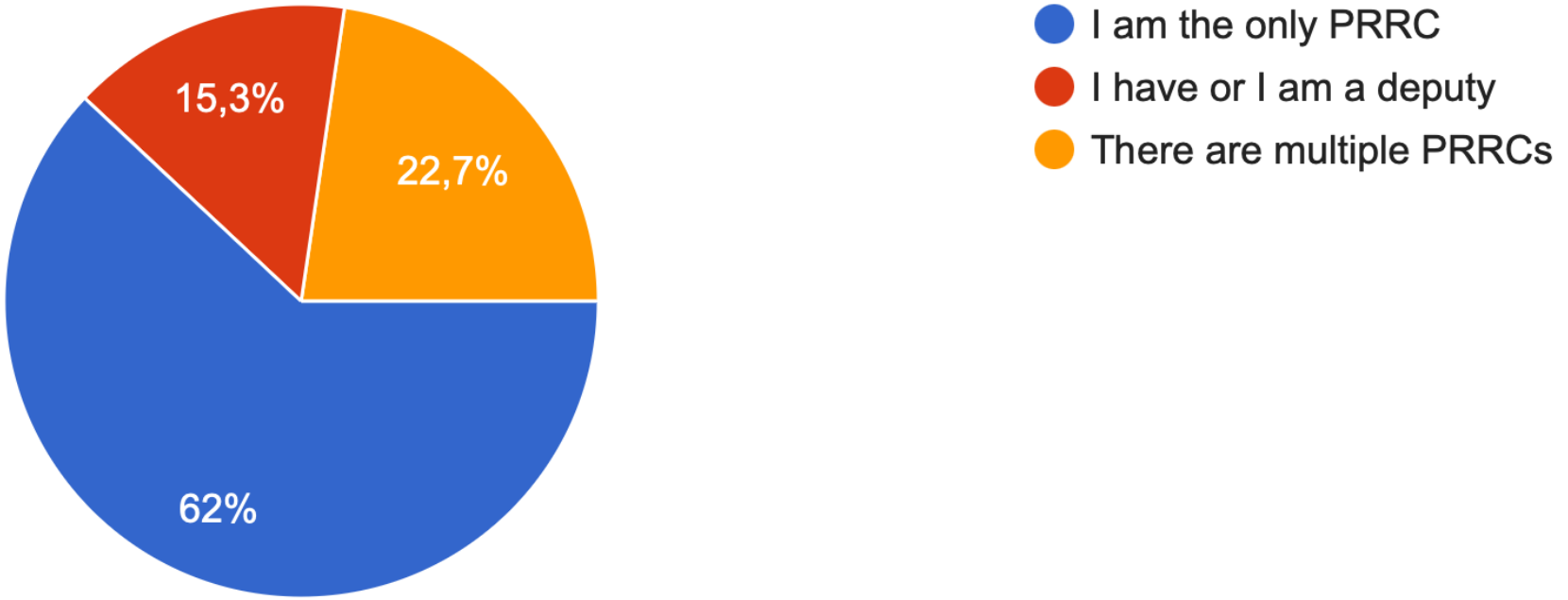
2. To know you better: What type of PRRC are you?

150 réponses



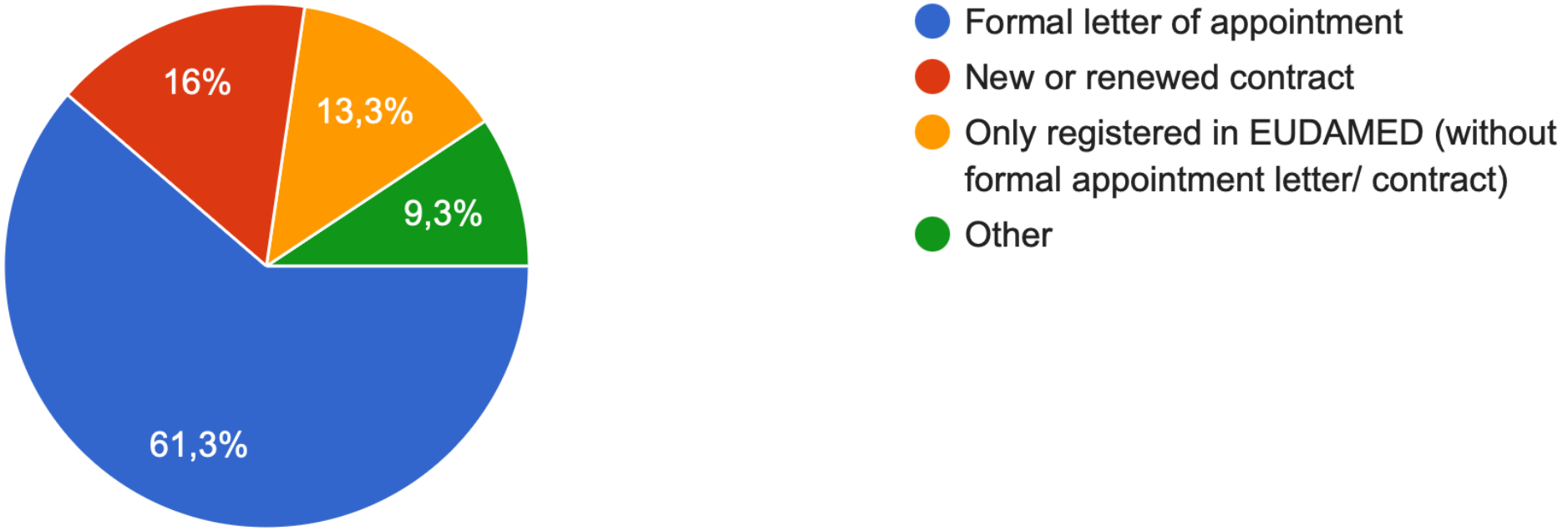
3. How many PRRCs are there in the company?

150 réponses



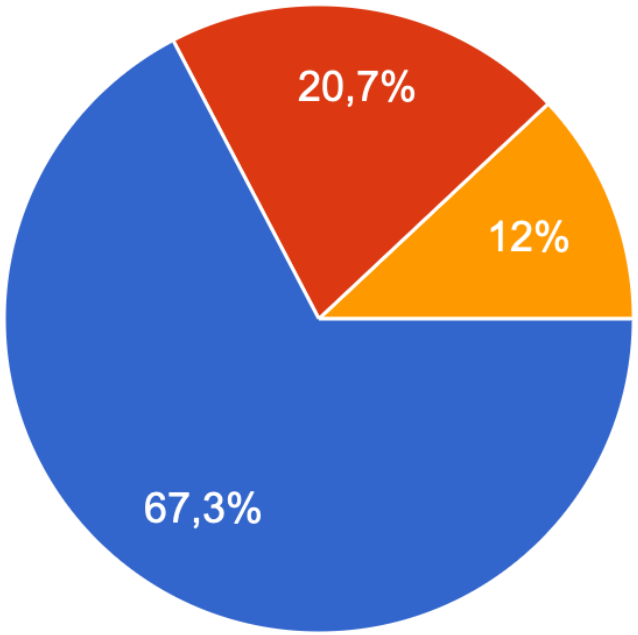
4. How were you designated as a PRRC?

150 réponses



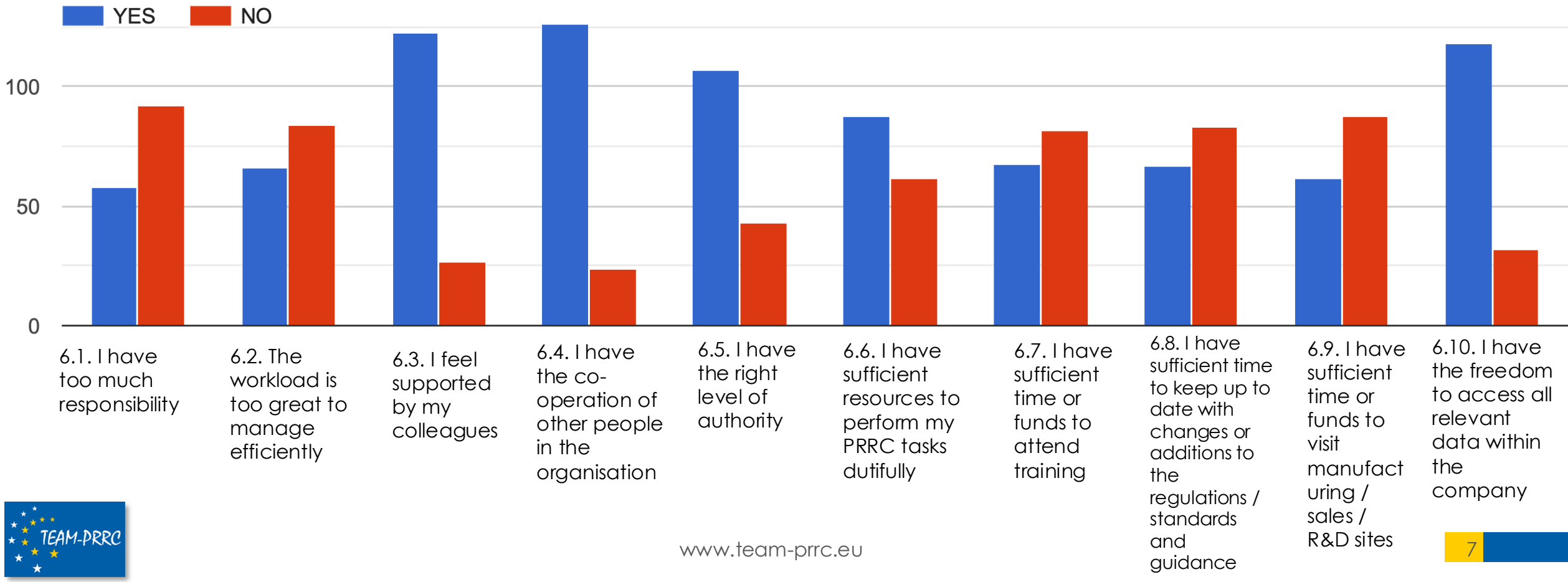
5. Did your organisation update your QMS procedures to integrate the PRRC's responsibilities?

150 réponses



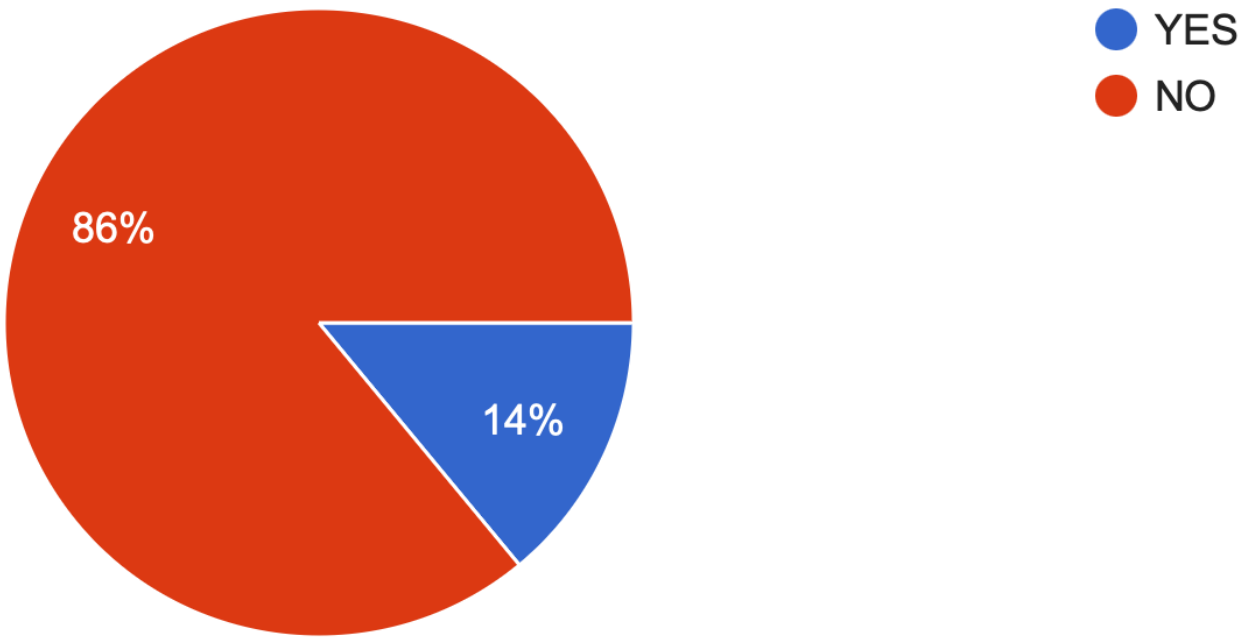
- Yes, the PRRC was added to existing procedures
- Yes, new procedures were created
- No, procedures have not changed yet

6. The following questions are intended to find out how comfortable people feel in their role as a PRRC;



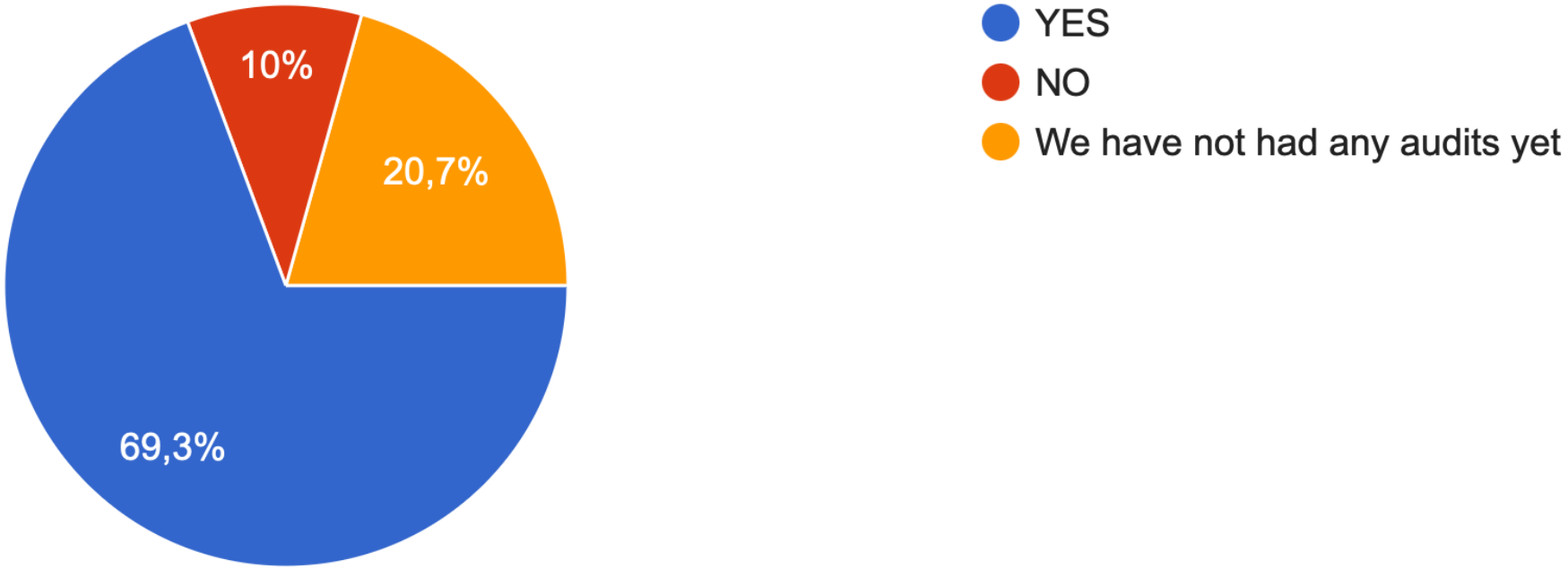
7. Do you think you have suffered any disadvantage performing the tasks in your role as a PRRC

150 réponses



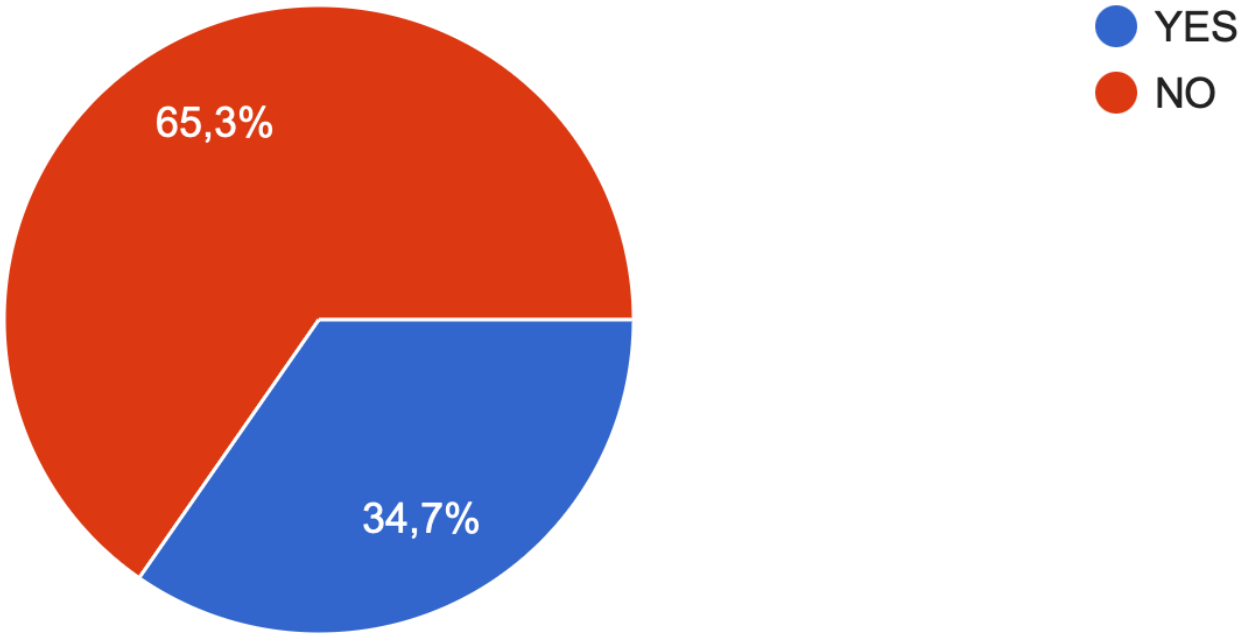
8. If you have had a CE or QMS audit since your appointment as PRRC, did it cover Art.15?

150 réponses



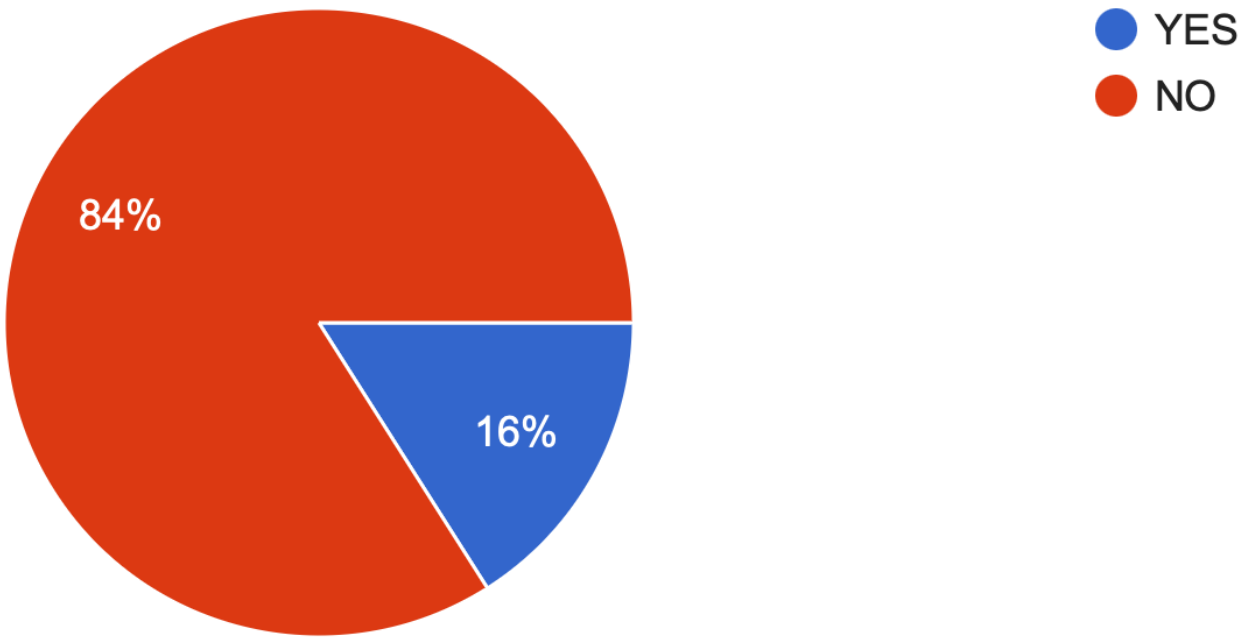
9. Have you been audited by one of the EU market surveillance authorities and did they check the implementation of Article 15 obligations?

150 réponses



10. Have you been scrutinized by the competent authority responsible for your organization after your registration in EUDAMED?

150 réponses



ANALYSIS OF THE RESULTS

The majority of respondents (60%) are PRRCs employed by a large company (>50 employees). Generally, they are the unique PRRC and have been formally designated with a formal letter of appointment.
For these people, the QMS has been updated so that the PRRC is included in existing procedures (67%).

86% of them think that they do no suffer any disadvantages. And for 69%, the audits realized covered the article 15. But only 34% have been audited by one of the EU market surveillance authorities and only 16% have been scrutinized by the competent authority responsible for your organization after your registration in EUDAMED.

The positive points are that the majority of the PRRC who answered the suvey feel supported by their colleague, and they have the co-operation of the people in the organization, with the right level of authority and sufficient resources to perform their tasks dutifully, they have the freedom to have access to relevant data and they feel that they don't have too much responsibility.
However, the workload seems to not be too good to manage efficiently, they don't have too many time or funds to attend trainings, or to keep up-to-date about the regulatory changes, and they don't have sufficient time to visit manufacturing/sales and R&D sites.

Questions ?

Please inform your colleagues about TEAM-PRRC. The more members we have the greater our voice!

THANK YOU FOR LISTENING

For more information about TEAM-PRRC go to:
www.team-prrc.eu or send us an email to : inform@team-prrc.eu