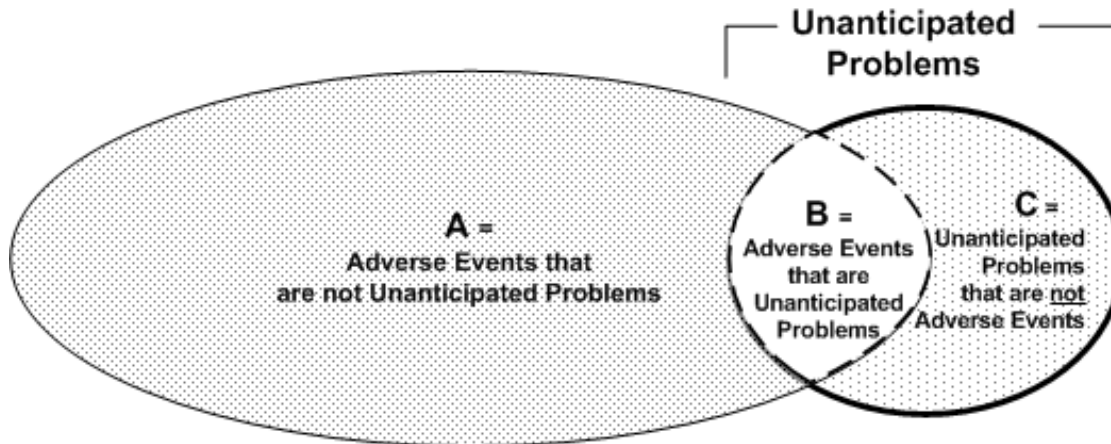


## How do you determine which adverse events are problems that are unanticipated?

The following Venn diagram summarizes the general relationship between adverse events and problems that are unanticipated:



**Under 45 CFR part 46: Do not report A; Report B and C.**

The diagram illustrates three key points:

- The vast majority of adverse events occurring in human subjects are not unanticipated problems (area A).
- A small proportion of adverse events are unanticipated problems (area B).
- Unanticipated problems include other incidents, experiences, and outcomes that are not adverse events (area C).