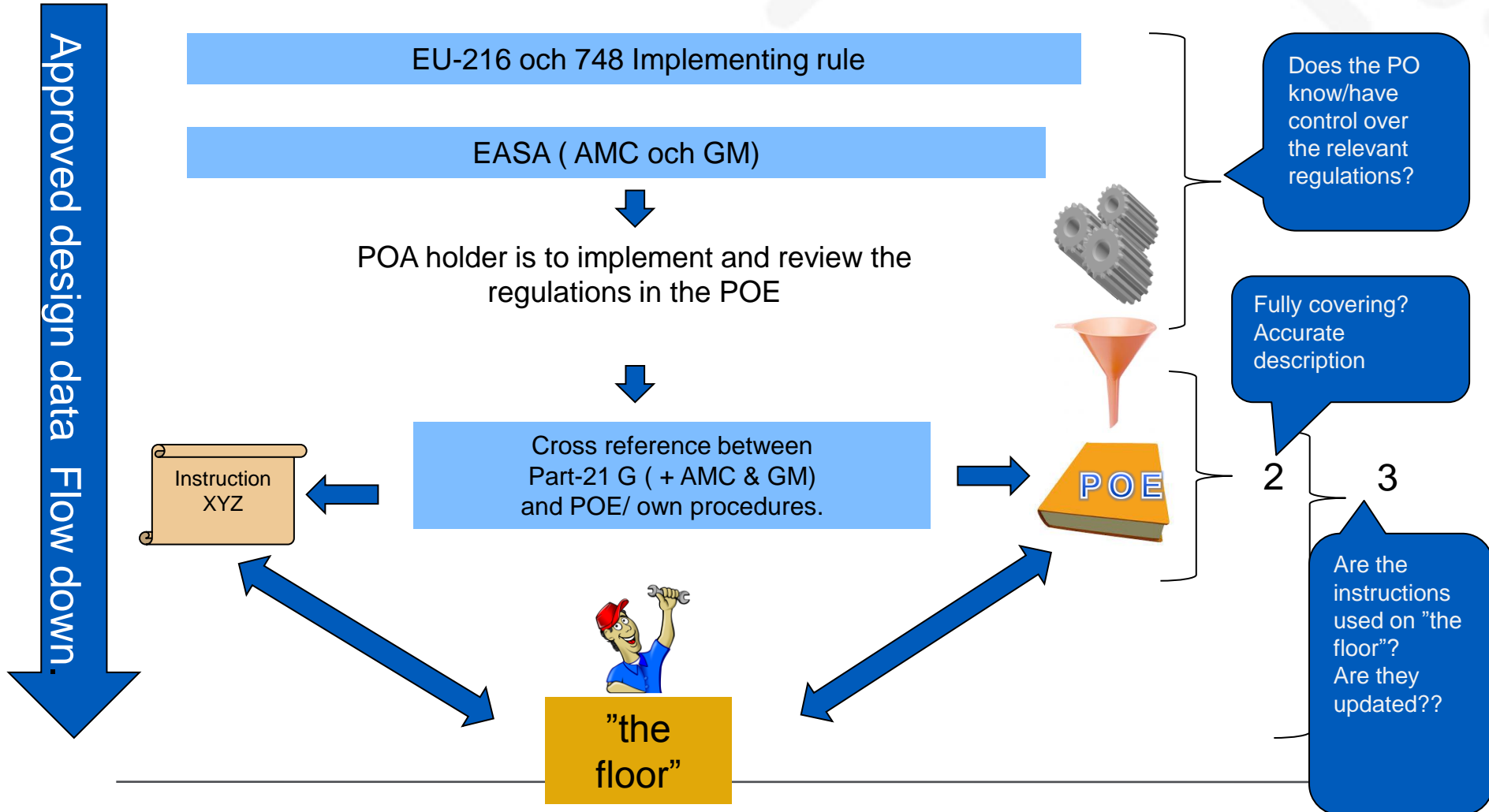


Vad tittar vi på ?



What are we looking for?

What

IR – Implementing Regulation

(748/2012)

How

AMC – Acceptable Means of Compliance

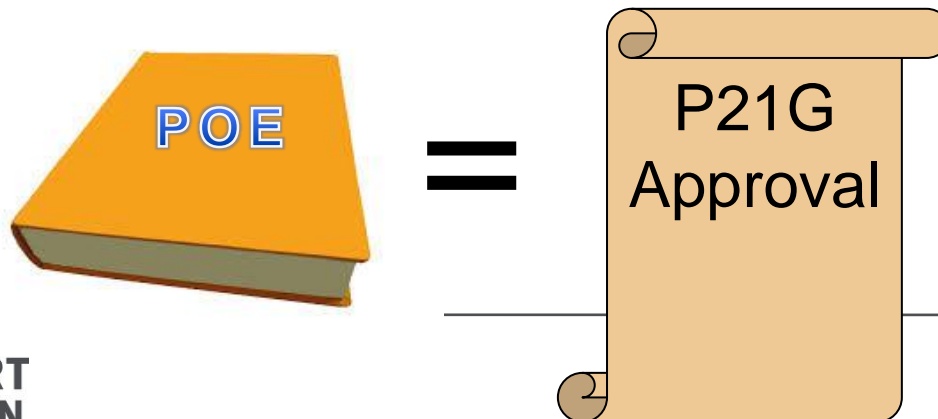
GM – Guidance Material

POE



GM 21.A.143 Exposition – Production Organisation Exposition (POE)

- The competent authority requires the **POE to be an accurate definition and description** of the production organisation.
- The document does not require approval in itself, **but it will be considered as such by virtue of the approval of the organisation.**



Whats the use...

"Good" POE

- Easy to see compliance
- Easy to audit
- Easy to work with
- Accurate/revised
- Fully covering the POA



"Bad" POE

- Compliance not ensured
- Hard to audit
- Hard to work with (sub routines)
- Procedures not up to date
- Not fully covering the POA

