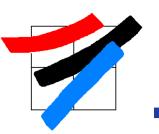


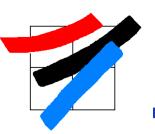
#### The Ad hoc group





# Agreed principles

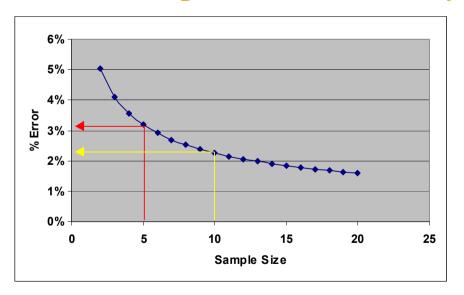
- > 3 phases
  - > Type approval
  - > Qualification of production
  - **Control Of Production**
- > Statistical Control based on:
  - > Mean value
  - > Standard deviation



## Sampling

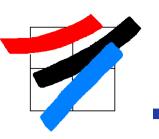
Clepa shows that 10 samples don't bring a lot more confidence than 5

#### **Effect of Sample Size on Accuracy**



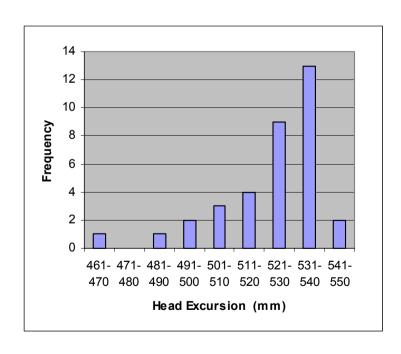
Using:- 
$$n = ((z \times s) / E)^2$$

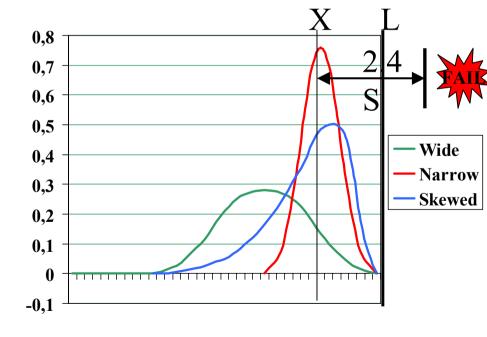
Where: E = Error, S = 20 / 550 and z = 1.96 for 95% confidence level

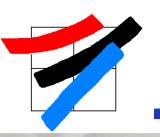


#### CRS population

Clepa shows that the repartition of the CRS population is skewed and not normal

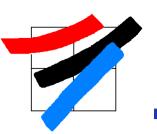






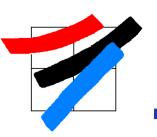
#### Qualification of the production

- With for maximum horizontal head excursion
  - $\rightarrow$  M + 1 x SD  $\leq$  Limit
  - $\triangleright$  no value ≥ 1.05 x Limit
  - on 5 samples
  - we are confident in the improvement of quality of the production
- Application of the first criteria to the 3 ms clipped resultant chest acceleration for information only



## Conformity Of Production

- > By batch control
  - Normal: 2 (+2) by batch between 500 and 5000 units => 0.04% (0.08%) (x 4)
  - > Strengthened: 4 (+4) by batch between 500 and 5000 units => 0.08% (0.16%) (x 5)
- > By continuous control
  - Normal: 0.02% of the production (x 41)
  - > Strengthened: 0.05% of the production (x 30)



#### Conclusions

- > Some add on:
  - > Control and recording of marking
- Application to Universal, Semi Universal and Restricted CRS
- ➤ Needs that approval Authorities must verify the conformity of production procedures of manufacturers during periodic visits