The Certification Process for a Radionuclide Laboratory

Radionuclide Workshop
AWE Aldermaston
January 29th – February 2nd, 2001
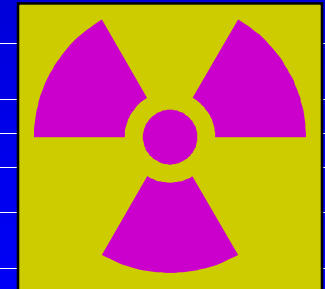
Chris Schmitzer, Martina Schwaiger
Austrian Research Center Seibersdorf

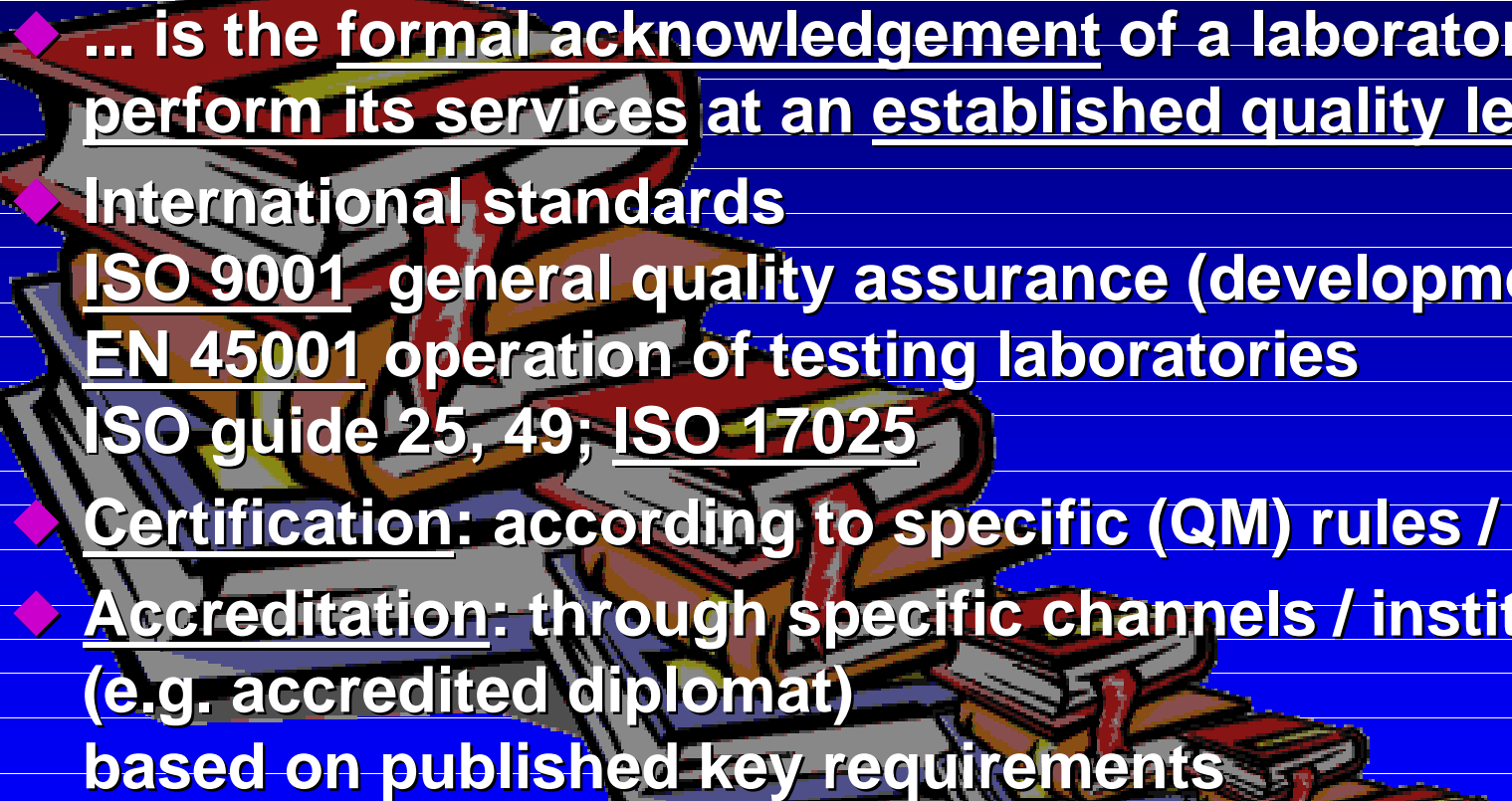# Introduction

to certify or not to certify ...

◆ **generalised concept
specific services
customer – supplier**

◆ **comparison**

Certification (by way of comparison)

- **... is the formal acknowledgement of a laboratory to perform its services at an established quality level**

- **International standards**
  ISO 9001 general quality assurance (development)
  EN 45001 operation of testing laboratories
  ISO guide 25, 49; ISO 17025

- **Certification: according to specific (QM) rules / specs**

- **Accreditation: through specific channels / institutuions (e.g. accredited diplomat)**
  based on published key requirements

Auditing – examination

- ◆ ... a process of inspection

- ◆ ... for products or services

   - **based on** -

- ◆ agreed quality level

- ◆ agreement customer – supplier

- ◆ singular / periodic

- ◆ acceptable cost implications

AUSTRIAN RESEARCH CENTERS

A simple phase model

- **Basic agreement**
- **Investment**
  - Hardware
  - Procedures
  - Materials (ref/std)
- **Operation**
  - Std. operation
  - Maintenance
  - Intercomparison
  - Auditing, training, ...
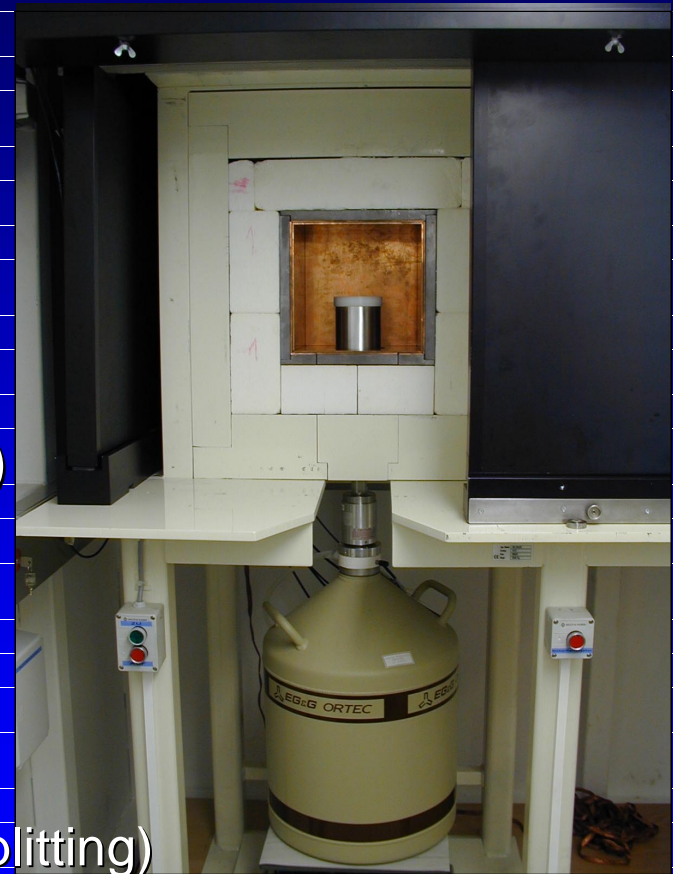
AUSTRIAN RESEARCH CENTERS

Application to CTBTO – stations

- ◆ „owned" by CTBTO
- ◆ **Specs**: discussed & accepted
- ◆ **Cost / benefit**: internationally accepted within budget margins
- ◆ **Realization**: primarily CTBTO
- ◆ **Certification**: CTBTO, based on agreed procedures
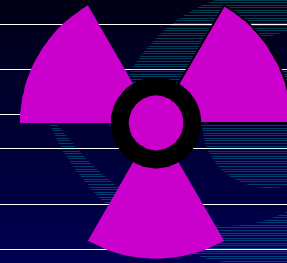- ◆ **Operation**: under contract

SNOW WHITE SENYA

AUSTRIAN RESEARCH CENTERS

Application to CTBTO – RN labs

◆ Not „owned" by CTBTO

◆ **Specs**: in discussion, challenging

◆ **Cost / benefit**: to be agreed

◆ **Realization**: P/P institutions

◆ **Certification**: CTBTO, procedures in discussion (INF.96)

◆ **Operation**: **fee-for-service**

◆ **Services:**

　➢ Stand-by (readiness)

　➢ Measurement

　➢ Miscellaneous (intercomp, sample splitting)

Prions vs. Nuclides:

Sensitive analysis	✓	✓
Standardized procedures (state-of-the-art)	✓	✓
Customer base	**many**	**single**
Parallel usage	✓	(✓)
Certification of laboratory / procedures	**proc**	**?**
... by neutral authority	✓	—
... by customer	—	✓
Competitive pricing	✓	✓
Additional services		
Stand-by	✓	✓
High thoughput	✓	—
Intermediate results	?	✓
Specs on		
Security, data proc, reporting	GLP	✓
Communication, equipment	—	✓
Personnel	GLP	—
Interference	NO	yes

Examples for strong customer ~~interference~~ INTERACTION

◆ **Defense / Military**
- ➢ **Inspection during development**
- ➢ **Inspection during production**
- ➢ **Inspection during testing**

◆ **Aerospace technology**
- ➢ **Similar to defense**

◆ **Medical products**
- ➢ **Multi-level scheme of certification**
- ➢ **CE testing**
- ➢ **HSE**
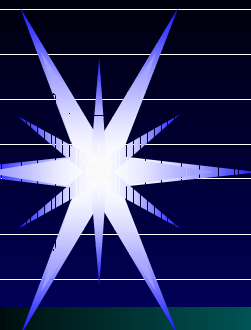
AUSTRIAN RESEARCH CENTERS

A long time ago ...

- ◆ **Geneva**

- ◆ **Standardized analytical service**
  ... commercial approach
  ... market value
  ... competitive pricing

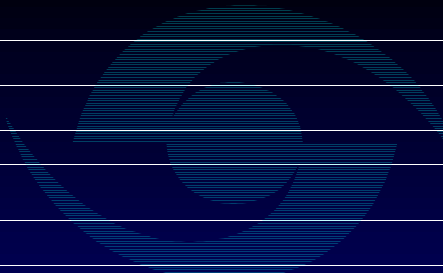- ◆ **Fee-for-service**

- ◆ **Commercial framework**

Treaty

The ALARA principle

◆ Customer-supplier relationship
fee-for-service

◆ Interference or Interaction?

◆ **Interference** – as low as
reasonably achievable

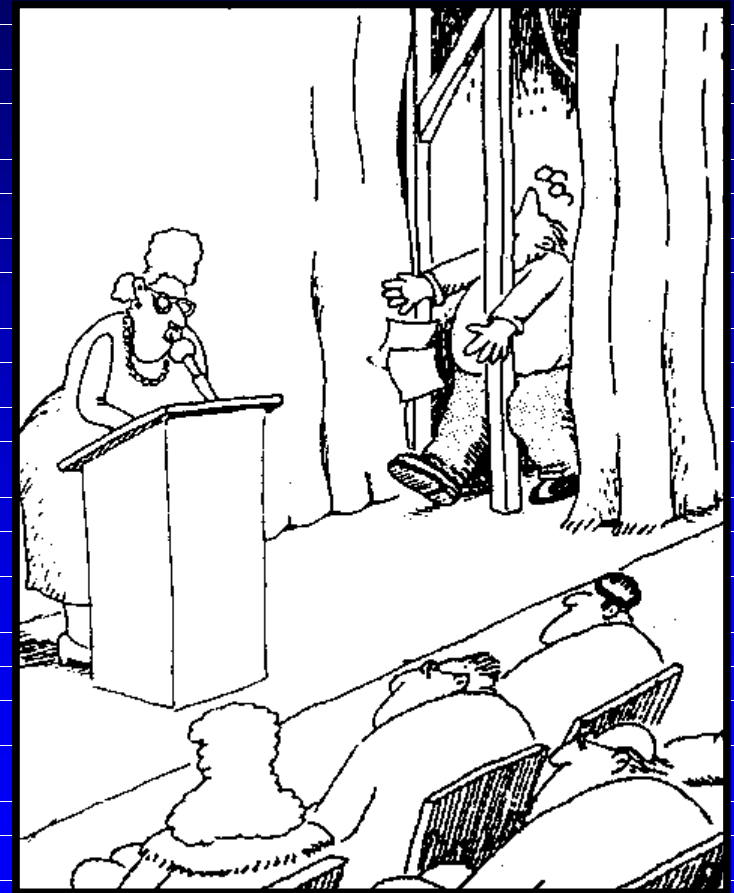◆ **Interaction** -
Costing implications

INF.96 / Rev.1

- ◆ English language / communication
- ◆ Audit & review findings fwd CTBTO
- ◆ Stand-by, on-call, ~ 6h response
- ◆ Intercomparison exercises
- ◆ Std. reference materials / traceability
- ◆ Special communications / mail server
- ◆ Bar codes for sample ID
- ◆ Reporting format / messaging
- ◆ Digital signature / authentication

AUSTRIAN RESEARCH CENTERS

Conclusions

- **'99 evaluation workshop** «you get what you pay for»

- **RN-labs are cooperating in certification procedures**

- **Services are being defined** ... « mind over matter »

- Interaction/Interference

- Certification requirements and services ➜ competitve pricing

AUSTRIAN RESEARCH CENTERS

The Testing Program