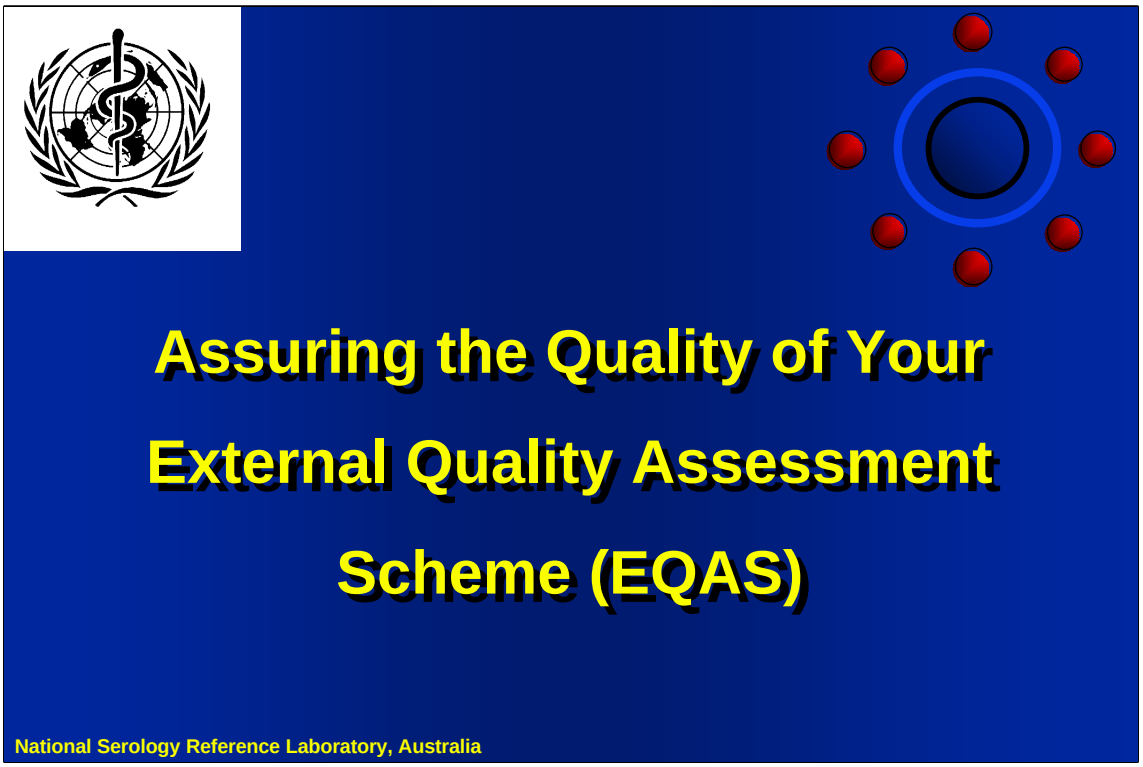


Definitions of terms used:

Accreditation: Approval by a body authorised to accredit that a laboratory or facility meets a given set of guidelines

Collaborator: An organisation that undertakes subcontracted activities for the EQAS provider.

External Quality Assessment Scheme (EQAS): Inter-laboratory comparison designed and operated to assure laboratory performance.

Guideline: A set of criteria which can be followed in order to improve the quality of your processes.

Panel: Each group of 8-10 specimens that are sent to participants.

Participant: A laboratory or organisation that elects to take part in an EQAS.

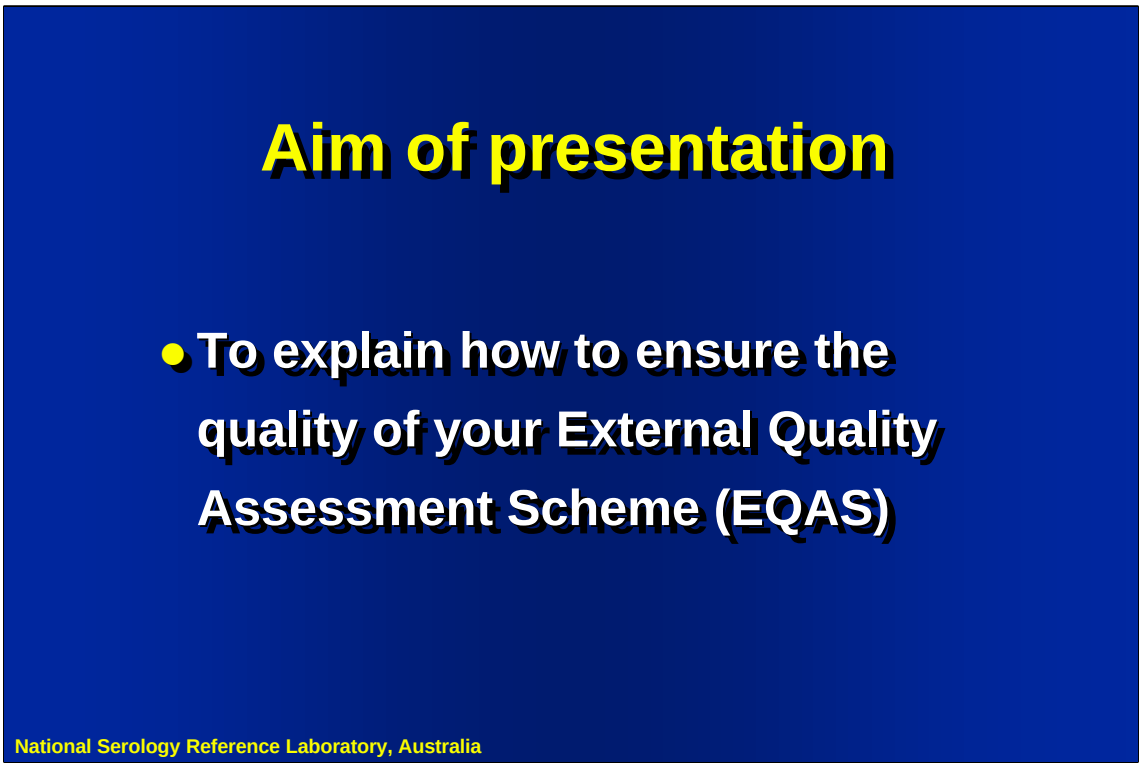
Proficiency Testing: Inter-laboratory comparison designed and operated to assure laboratory performance.

Provider: An organisation that undertakes the design and conduct of an EQAS.

Quality: Degree to which a set of inherent characteristics fulfils requirements.

Quality Management: Coordinated activities to direct and control an organisation with regard to quality.

Quality Management System: A management system to direct and control an organisation with regard to quality.



Aims of the presentation

I was asked to talk about how to ensure the quality of your EQAS.

The information in this presentation will also help you to assess other quality EQAS in which you might participate.

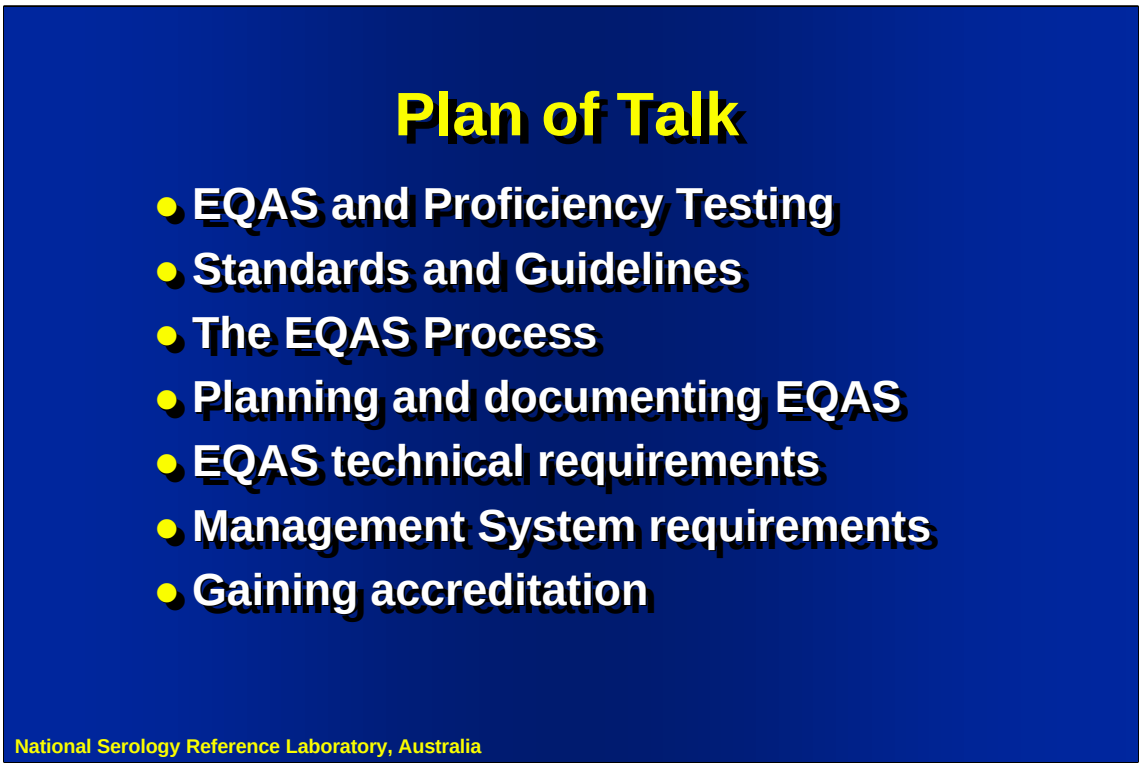
Objectives:

To offer guides to ensure adequate planning for an EQAS.

To detail the process involved in providing EQAS.

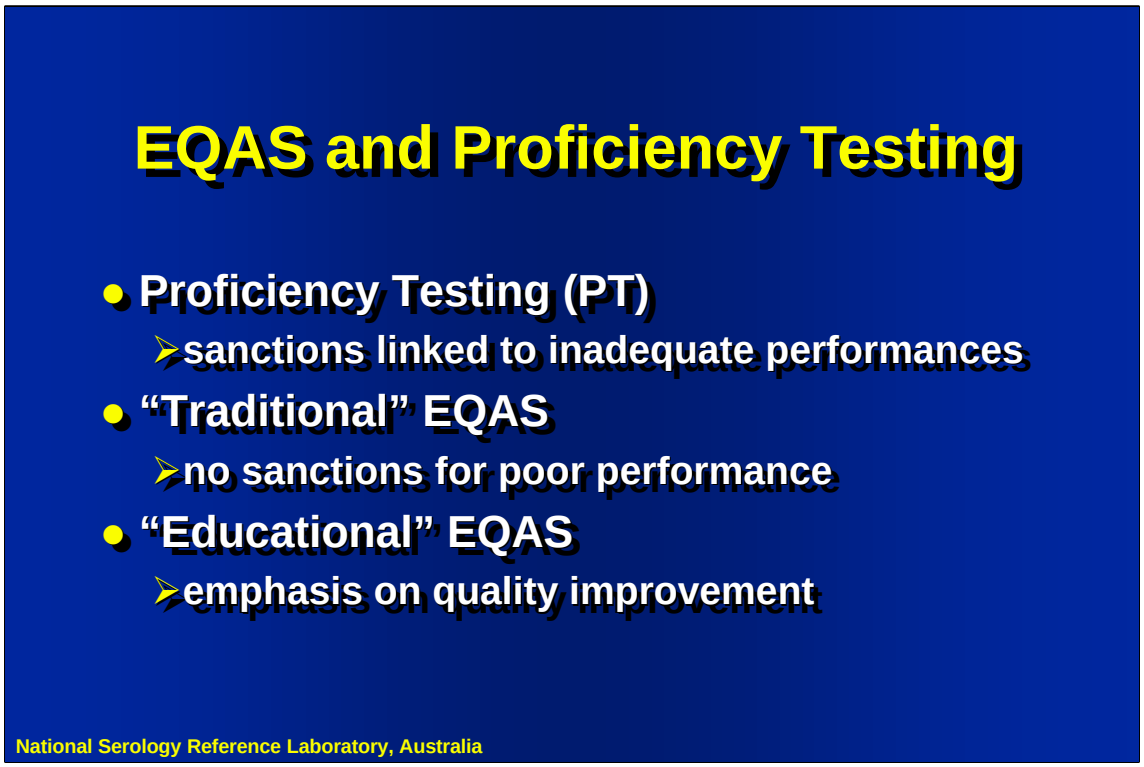
To teach you to assess the quality of another EQAS.

Explain how to run a quality EQAS and obtain accreditation of your laboratory.



Plan of talk

- EQAS and Proficiency Testing - the different types of proficiency programmes available.
- Standards and Guidelines - international guidelines to achieve quality
- The EQAS Process - explain steps involved in providing an EQAS.
- Planning and documenting the EQAS process - Documentation and planning required to provide a quality EQAS.
- EQAS technical requirements - quality issues involved in each step of the EQAS process.
- Management System requirements - documentation and methods to achieve a quality management system.
- Gaining accreditation - steps to gaining accreditation for providing and EQAS.



Types of EQAS

There are different types of proficiency programmes available. I have taken these definitions from a Reference by Libeer, 1996.

•Proficiency Testing (PT)

Sanctions are linked to inadequate performances. For example the laboratory may be required to repeat the testing or even be disaccredited from testing.

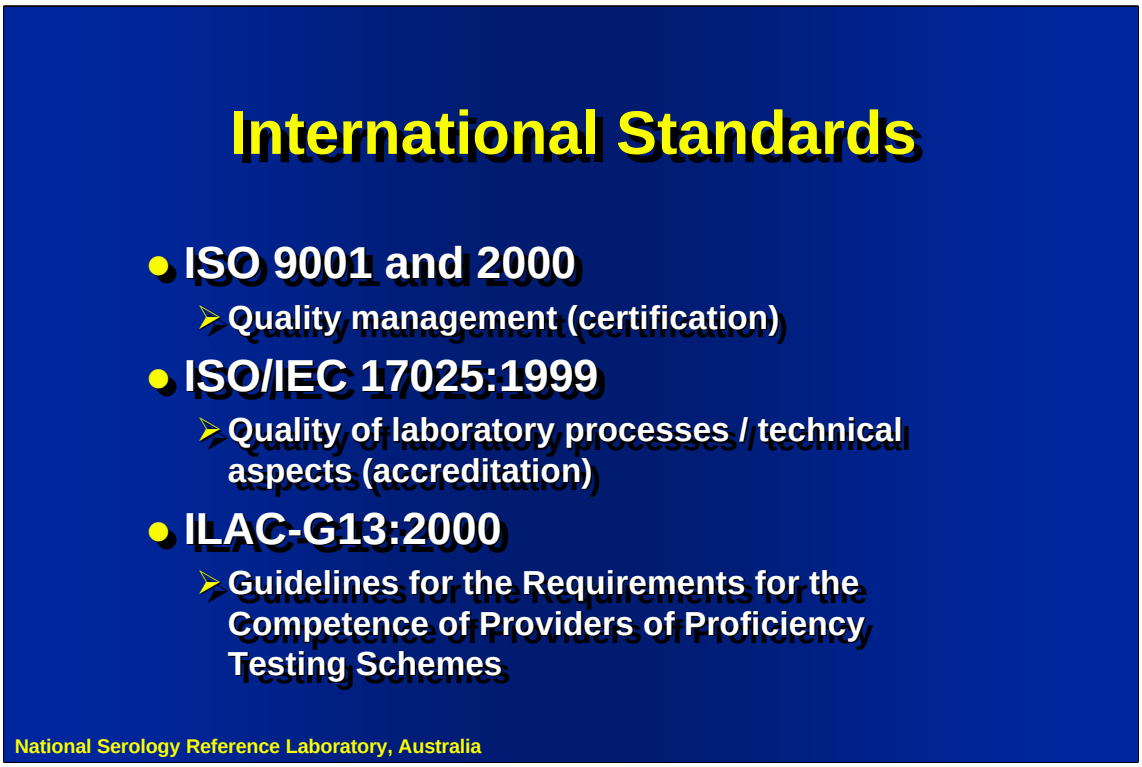
•"Traditional" EQAS

No sanctions for poor performance. Performances may be scored but there are no consequences for the laboratory. Most EQAS will fall into this category.

•"Educational" EQAS

Emphasis is on quality improvement. The scheme may include long-term follow up and assessment of quality improvement. Such schemes have a much larger scope than the other schemes.

This presentation will focus on EQAS.



International standards

Once you have decided (or been designated) to provide an EQAS there are standards and guidelines that can be followed.

Use these as guides to improve the quality of your laboratory on a continuing basis.

There are many standards and guidelines. The following are internationally used standards:

The ISO 9001 standards focus on Quality Management and Quality Assurance

ISO/IEC 17025:2000 standards are General Requirements for Calibration and Testing Laboratories

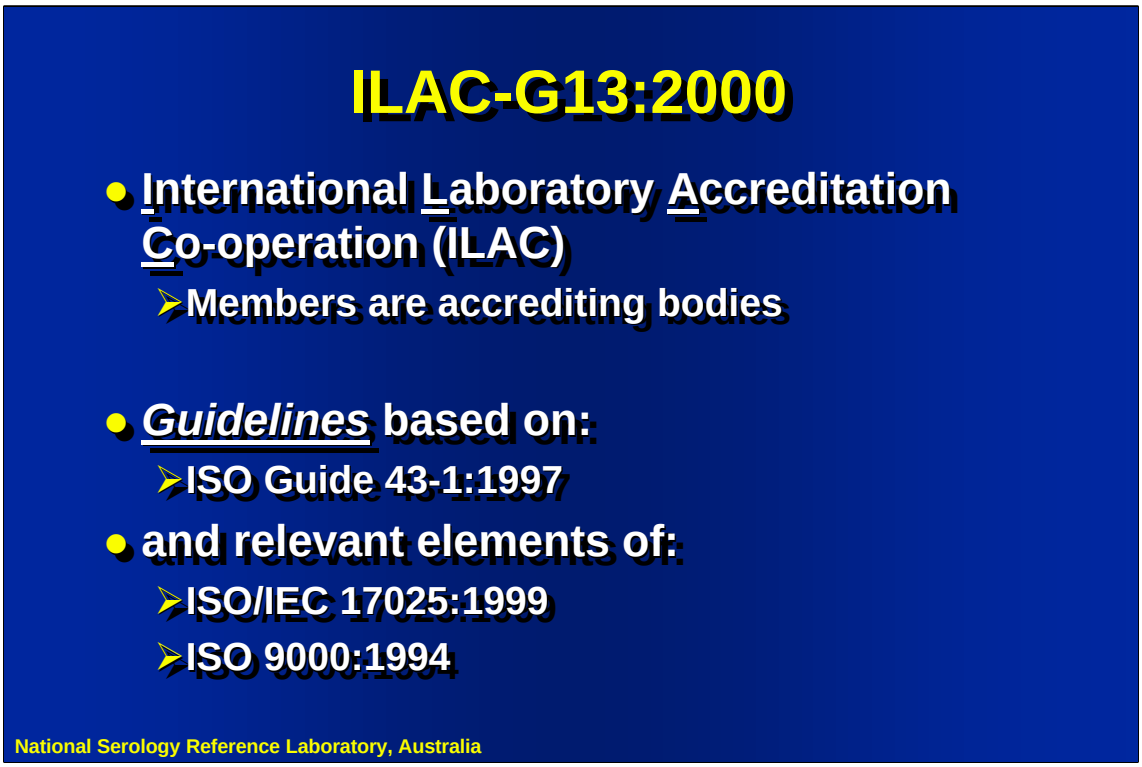
ILAC-G13:2000 - more specific Guidelines for the Providers of Proficiency Testing Schemes

Abbreviations and definitions:

CLIA = Clinical Laboratory Improvement Amendments of 1988

ISO = International Organization for Standardization

ILAC = International Laboratory Accreditation Co-operation



ILAC-G13:2000 = Guidelines for the requirements for the competence of providers of proficiency testing schemes

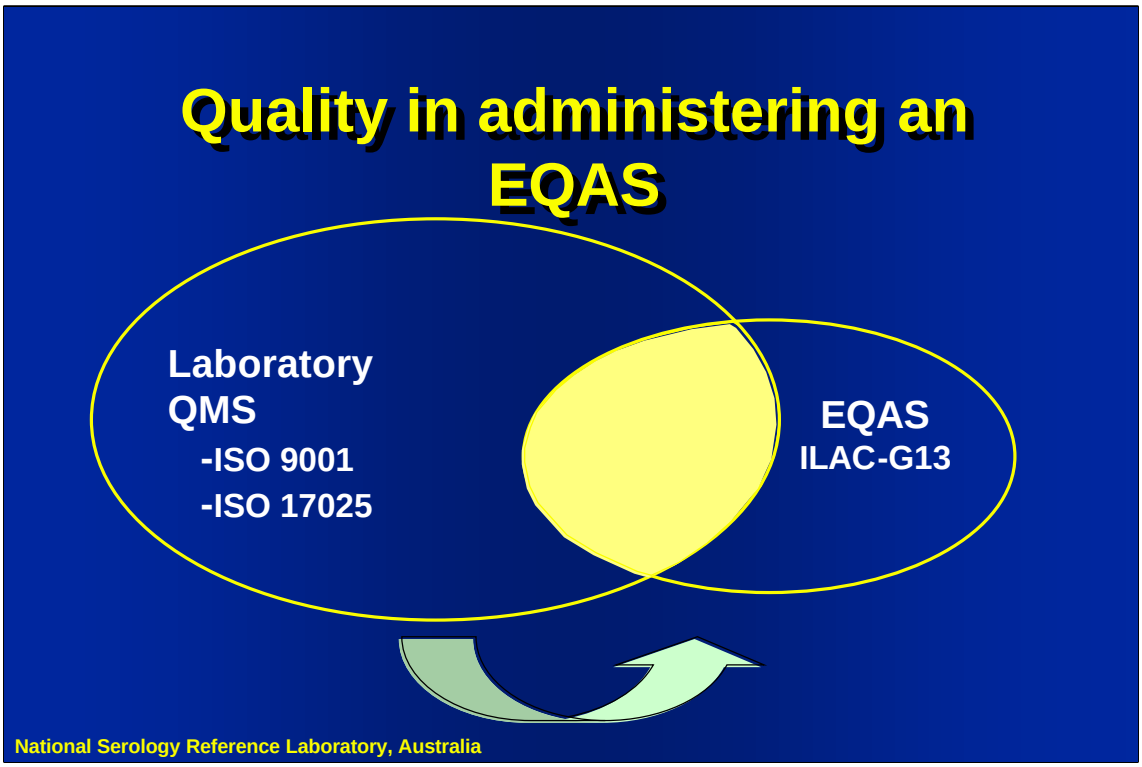
Guidelines are not international standards.

ILAC-G13:2000 is based on an earlier version called ISO Guide 43-1:1997.

The guidelines are written for laboratories that wish to develop and operate EQAS.

ILAC-G13:2000 includes relevant elements of ISO/IEC 17025:2000 and ISO 9001 to eliminate the need for separate recognition of a provider of EQAS in both.

ILAC-G13:2000 can be used to guide all steps involved in running an EQAS.



Quality in administering an EQAS scheme

If a laboratory decides or is designated to run an EQAS there are standards and guidelines that offer the necessary steps and requirements to achieve quality.

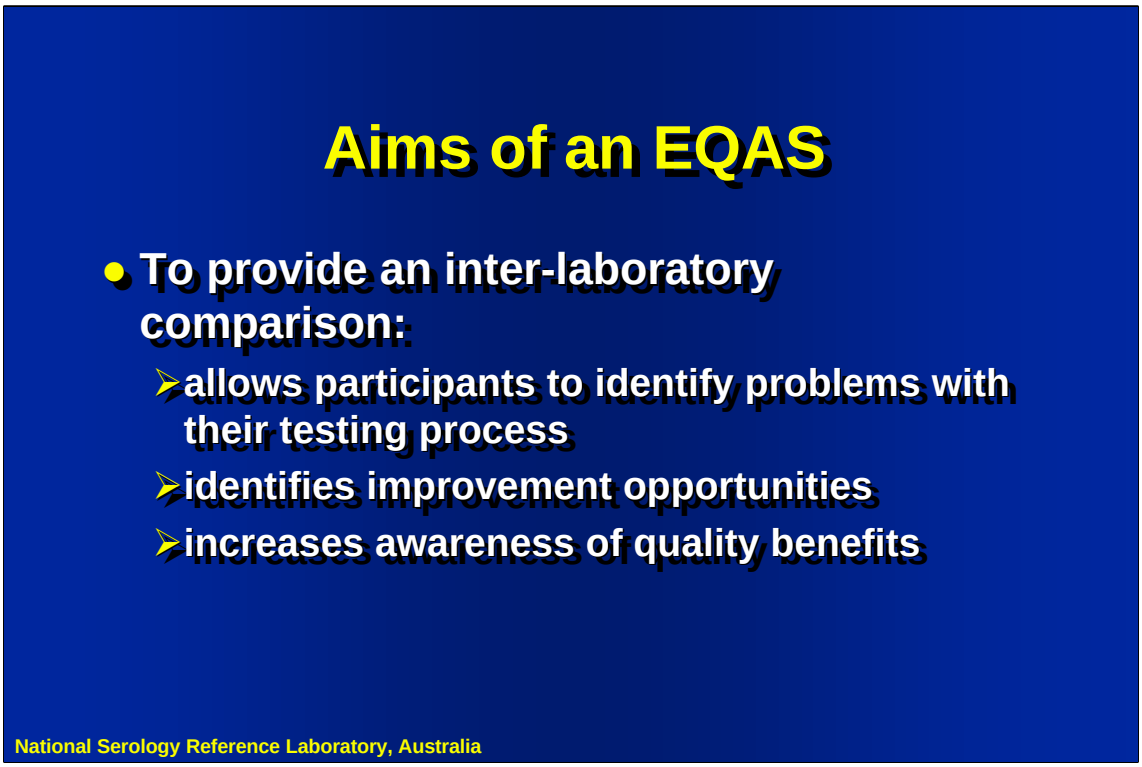
An EQAS provider should set an example for the participants by aiming for continuous quality improvements.

There are standards which cover the Quality Management system and the more technical aspects of laboratory testing.

The EQAS has its own processes and its own quality issues. ILAC-G13:2000 can be used to guide the quality of these EQAS processes.

However, a lot of the quality issues will be similar and should not be viewed separately

e.g. the quality of testing should be of the same standard when testing samples for diagnosis or for an EQAS panel.



Aims of an EQAS

•In order to run a quality EQAS, we need to be aware of why we are providing the EQAS

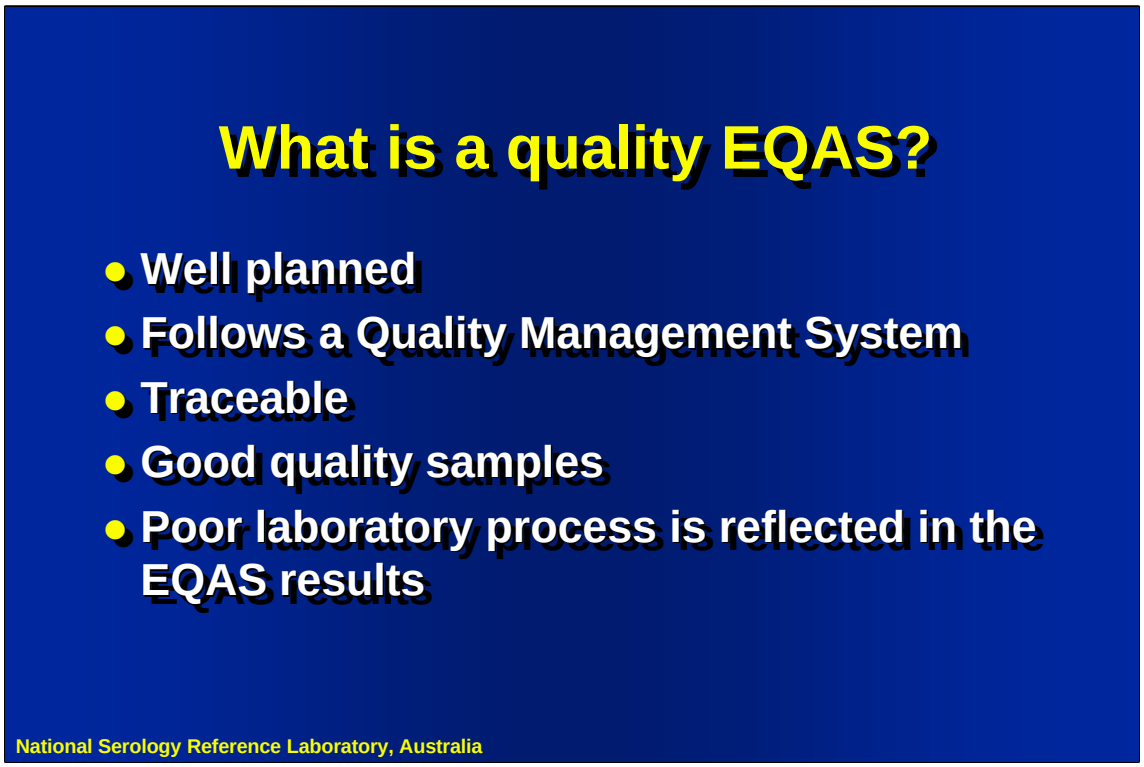
•An EQAS allows laboratories to compare the quality of their testing process to other laboratories.

Poor performance relative to other laboratories may:

•allow participants to identify problems with their testing process.

•identify improvement opportunities.

•Participation in an EQAS can increase the awareness of quality in the participating laboratories.



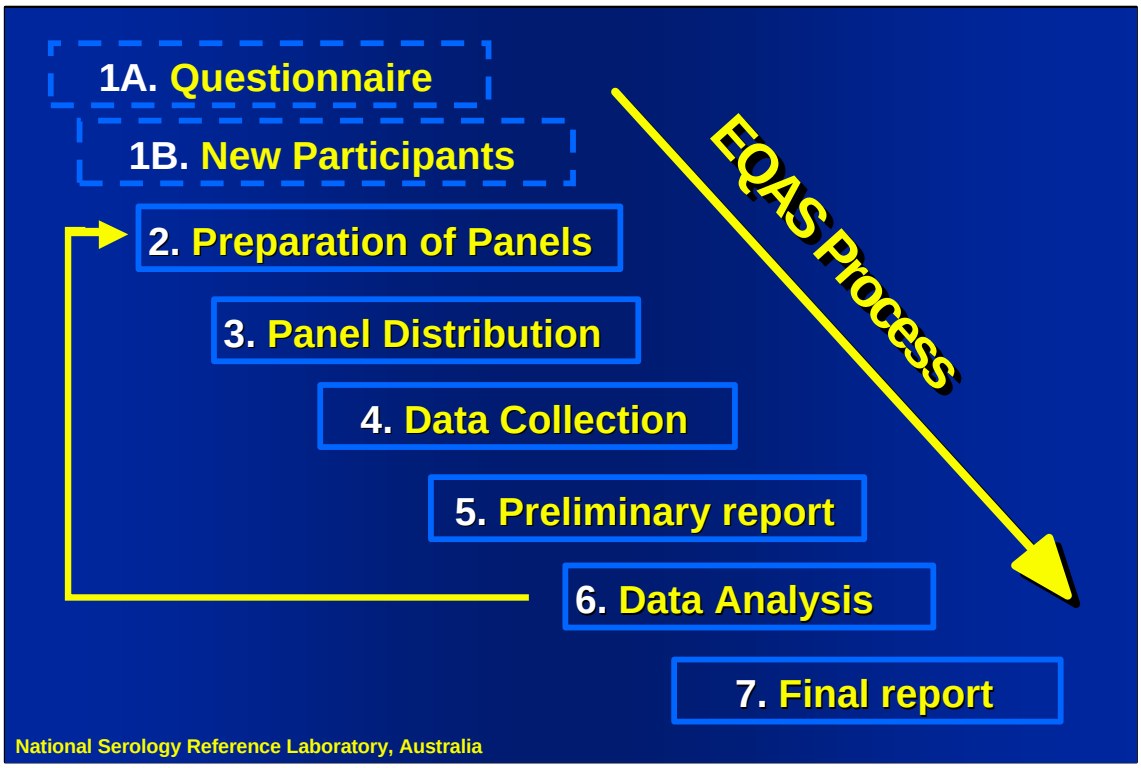
What is a quality EQAS?

A quality EQAS will be well planned and the entire process will be well documented.

A Quality Management System will ensure that improvements are continually strived for.

Each step of the EQAS process will be traceable.

Good quality samples. Ideally, the poor results are not due to errors made by the EQAS provider.



The EQAS process

A summary

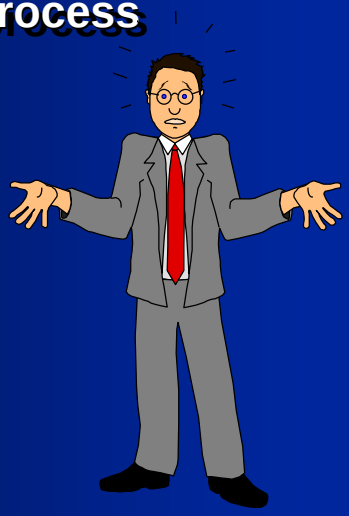
The steps involved in the EQAS process include:-

1. **Planning and Information gathering:** An initial questionnaire is sent to determine which tests are used by prospective participants as well as other information such as the testing strategy used.
2. Panel preparation - *selection, testing, aliquoting and packaging of samples*.
3. Distribution of the panel- *transport and preservation of samples*
4. Results are collected from each laboratory - *communication methods and mechanisms must be established.*
5. Preliminary report containing reference results is forwarded to the participant in order to give immediate feedback.
6. Once all results are received these are collated and analysed so that results may be compared.
7. A final report is forwarded to each participant so that the results can be used.

These are the headings that will be used throughout the rest of the presentation.

Planning and documenting EQAS

- For every step of the EQAS process try to decide:
  - Who?
  - What?
  - Where?
  - When?
  - Why?
  - How?



National Serology Reference Laboratory, Australia

If the EQAS provider can answer (and document) all the questions for every step of the process you are well on your way to developing a quality EQAS.

Take sample production for EQAS panels as an example:

•**Who** is responsible for co-ordinating the sample selection, testing and production?

•**What** testing should be done to characterise the samples?

•**What** company will be used to ship the samples to participating laboratories?

•**What** paperwork will be included with the samples?

•**What** type of samples will be selected (and who will do this)?

•**Where** will the testing be done (and by whom)?

•**Where** will the aliquotting of samples into smaller volumes be done (and by whom)?

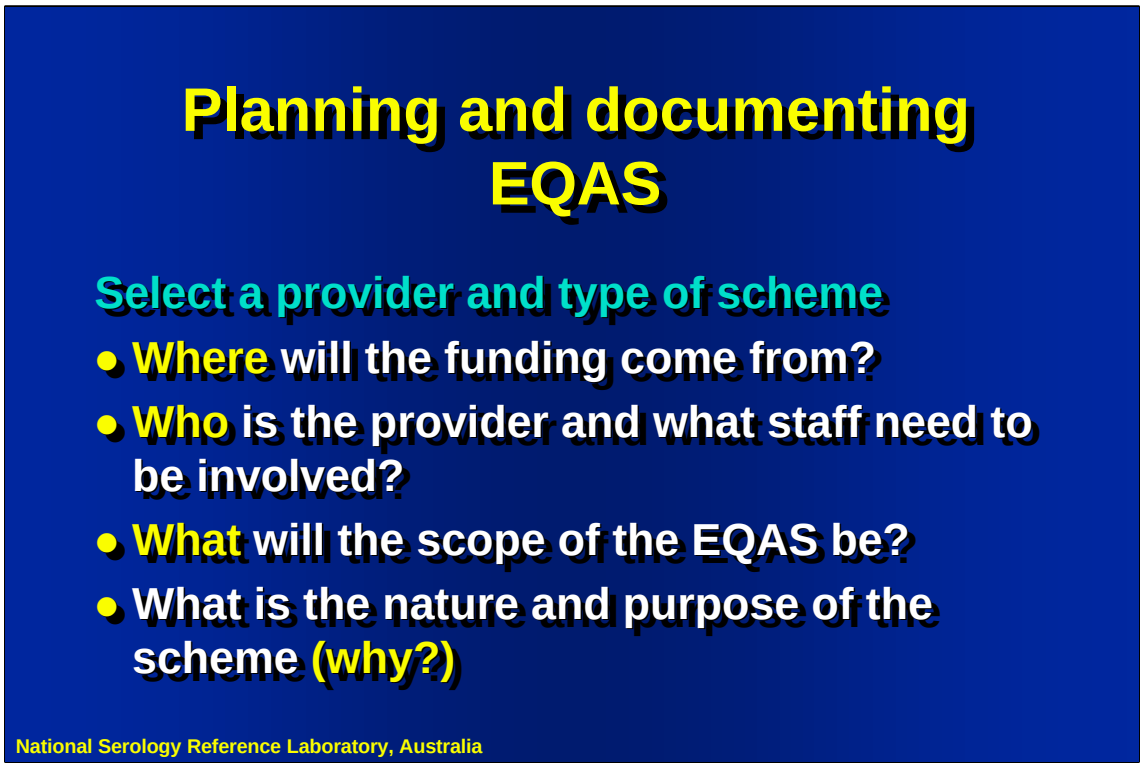
•**When** do the samples need to be shipped out?

•**Why** is the panel being sent out? For example, why send a majority of HIV subtype B positive samples when the majority of infections in the country are of subtype E?

•**How** much volume of each sample will we need?

•**How** will samples be packaged for shipping?

•And so on……..



Select a provider and type of scheme

During the planning of an EQAS the first thing that must be decided is, who will be the provider and what type of scheme will it be?

During planning, decide where will funding come from?

- A quality EQAS provider must have adequate funds for staff, premises, laboratory testing, computer and software, shipping etc. Without adequate funds the quality will be compromised

Who is the provider of the EQAS and who are the staff involved?

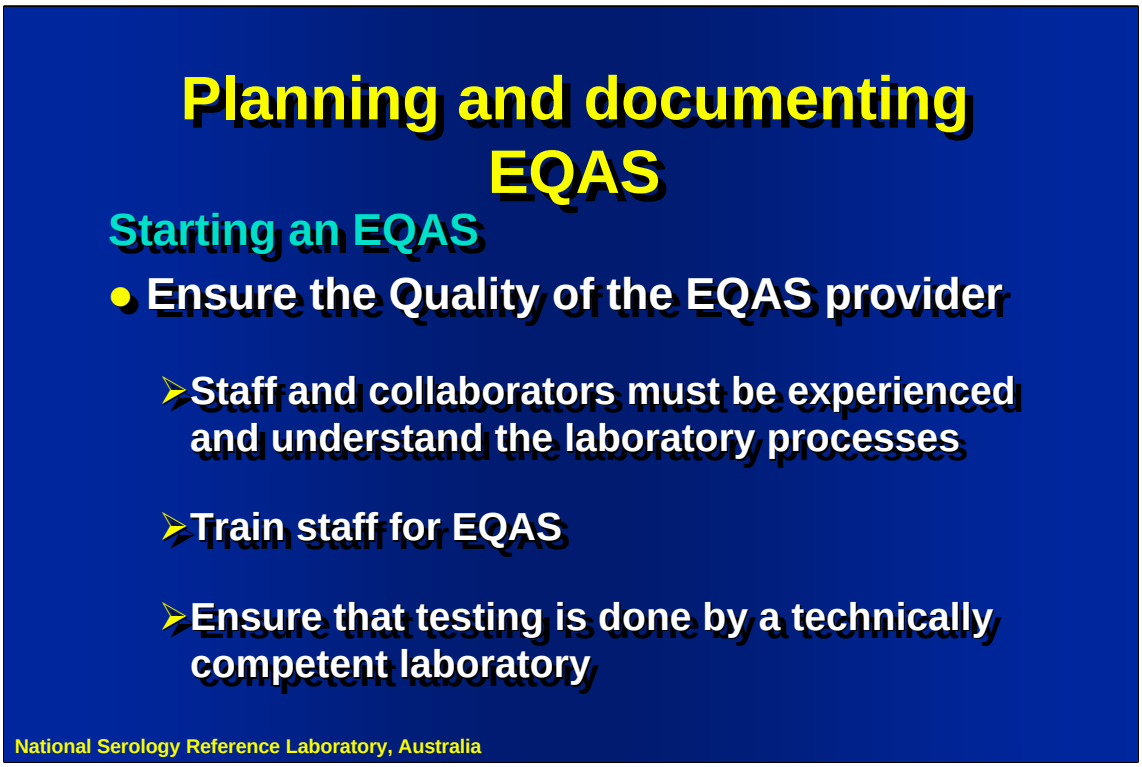
- Publicise the organisers names and addresses so that participants can contact them

What will the scope of the scheme will be?

- Is the scheme regional, national or international?

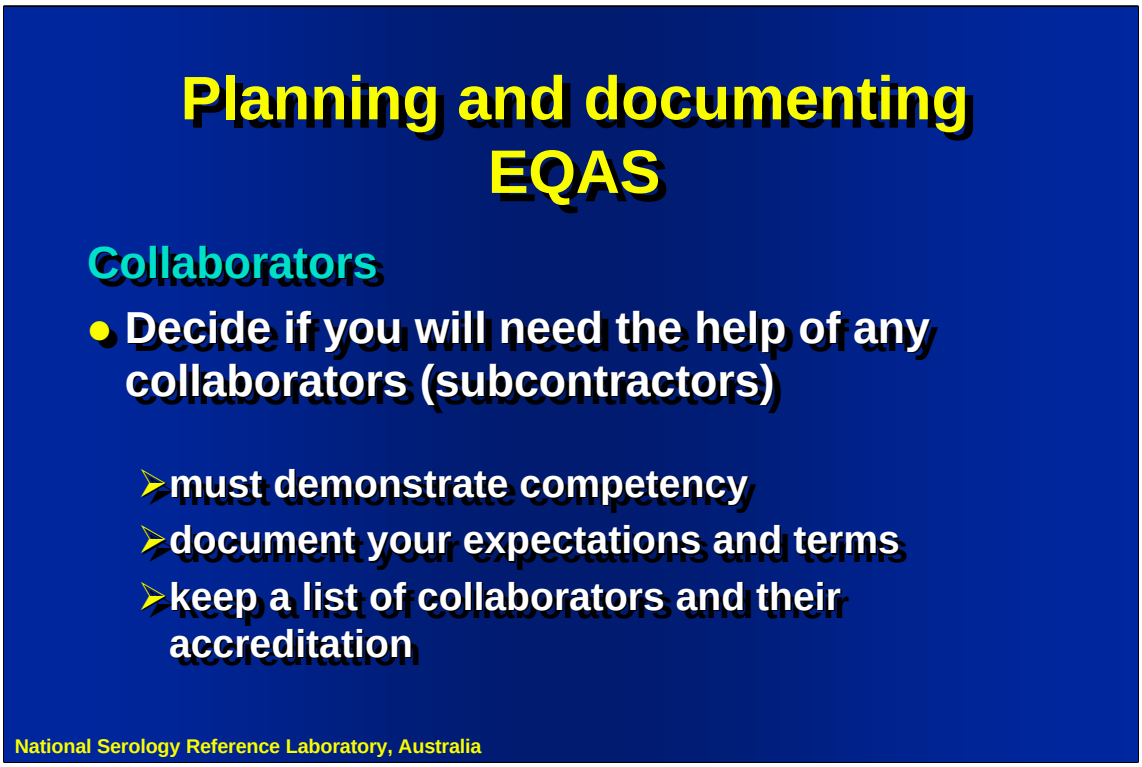
What is the nature and purpose of the scheme

- ie why are you providing the EQAS



Ensure the quality of the EQAS provider

- Staff and collaborators must be technically competent to provide the EQAS. This means that the **personnel should have appropriate education, training, technical knowledge and experience for their respective duties**.
- Staff should be trained as appropriate
- Ensure that testing of potential panel samples can be done by a technically competent laboratory. **The laboratory does not have to be accredited but should have an operating quality management system** so that they are demonstrating quality improvement.



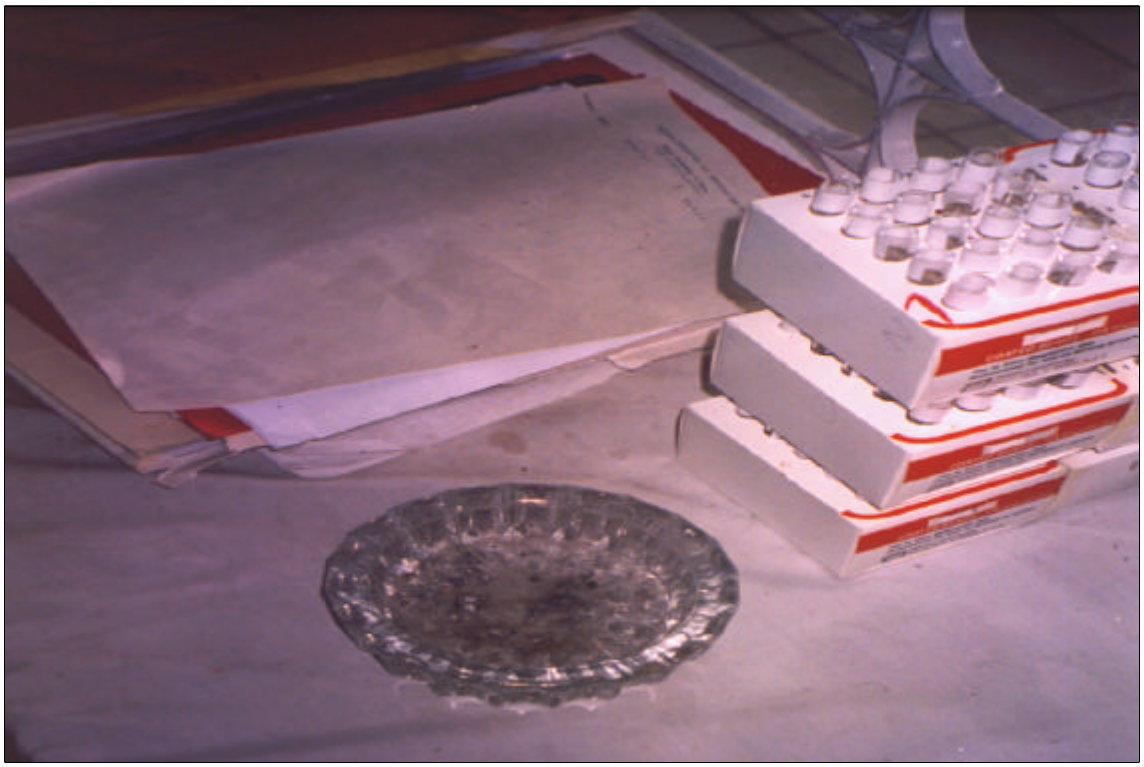
Collaborators

If the EQAS provider needs the help of collaborators, show that the collaborators are technically competent. It is helpful to document criteria for assessing a technically competent collaborator during the planning stages.

Criteria may include an established quality management system, demonstration of a system for quality improvement, staff training programmes, accreditation to a guideline (national or international), etc.

It is helpful to document expectations and terms of any collaborations. Even if a formal contract is not set up this will help with identifying the requirements of each party. It will save confusion later when the results are sorted out.

For example: do you want the collaborating laboratory to provide the results of many tests or to use a defined testing strategy to establish the sero-status of the sample. A defined sero-status may be more helpful in interpreting EQAS results.

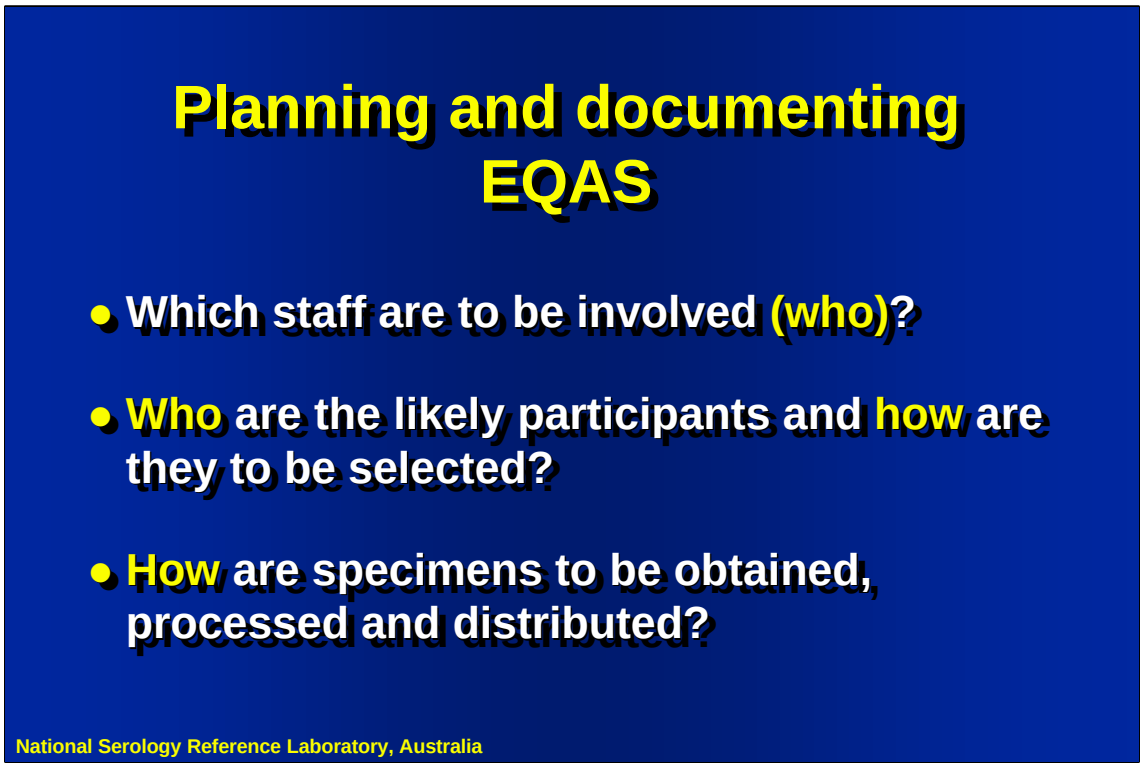


Do not want a collaborator with poor laboratory practices.

•Ash-tray next to samples with open tubes - presumably someone smokes while they work. *Putting something in their mouth*.

•Samples left next to paperwork

This is a laboratory. Someone is storing food and drink containers on the work bench.



A plan should be prepared and agreed upon by all staff before commencing the scheme. It should include:

Who are the staff involved?

- Names and addresses so that participants can contact them. These staff will need to be properly trained and have the appropriate education to perform their duties.

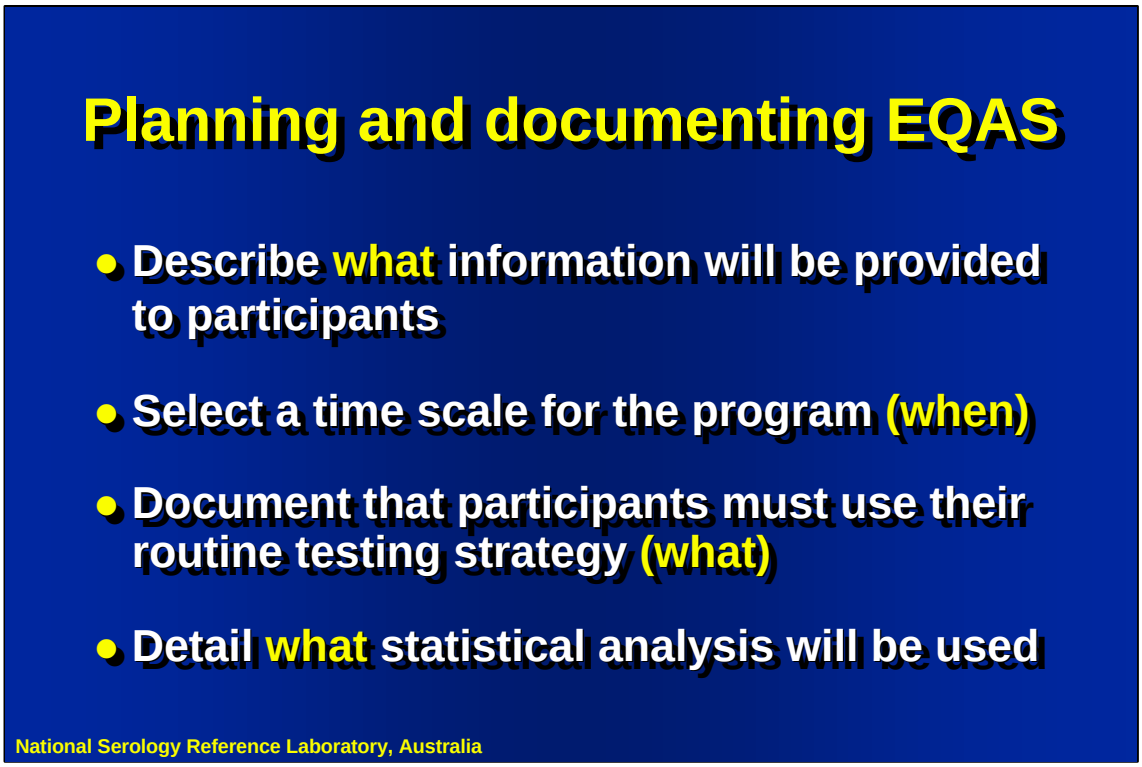
Make a list of likely participants and how they are to be contacted

- Decide on any criteria to be met before participation is allowed.

Decide how specimens are to be obtained, processed and distributed.

- Are they purchased or obtained by donation from participants?
- Are the specimens to be centrifuged and stored at -20ºC or aliquotted into smaller volumes first?
- Are the specimens to be distributed at ambient temperature or packed on ice? This will affect the type of packaging needed and the cost of shipping.

•<u>Document these decisions</u>



Planning and documenting EQAS

- **Describe the information that will be provided to ensure that participants understand the scheme. Describe the process, aims, objectives and material as well as the expectations of the provider**

  e.g. *"An 'early warning' letter will be drafted and distributed in January 2001 to inform laboratories of the expected number and type of samples and the approximate dates that panels will be distributed for the year 2001".*

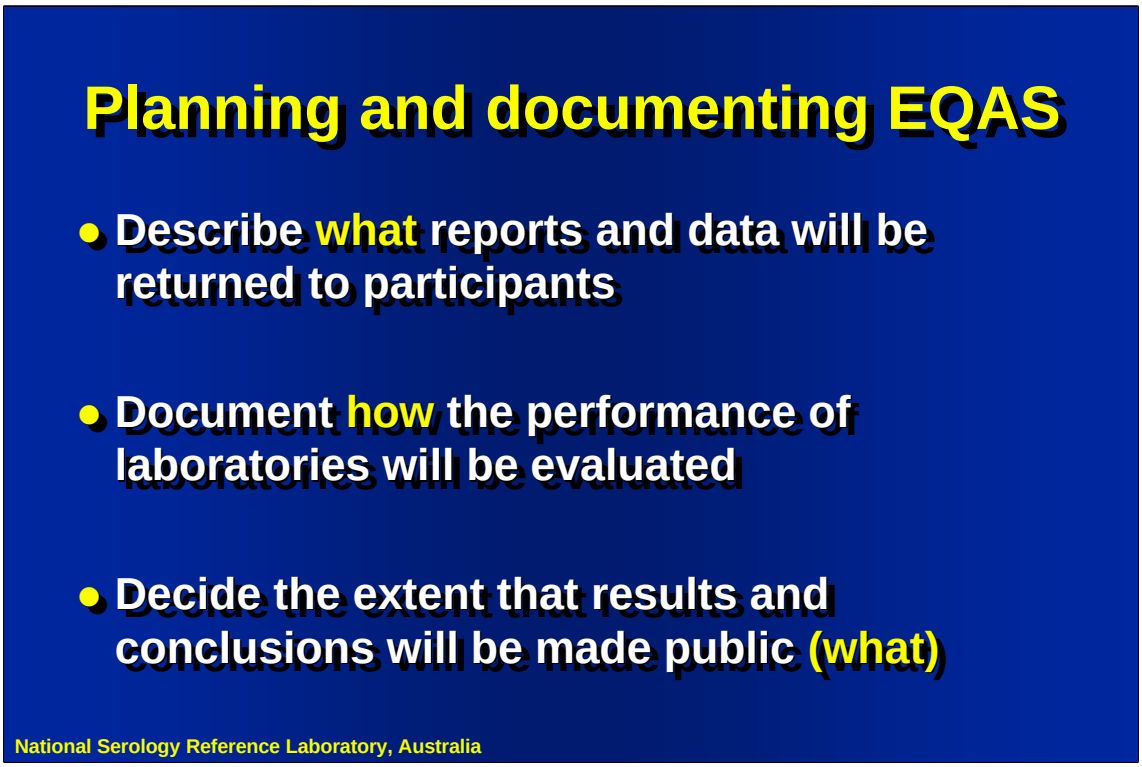
- **Select a time scale - when will panels be sent out, are there any deadline dates for participants**.

  e.g. *"Panels of approximately ten serum or plasma samples will be sent to each site in the first week of April, August and December. Laboratories should have performed testing and returned results within 30 days of receiving the panel. Laboratories will be informed of the due date in the cover letter that is sent with the samples (see attached)."*

- **Document the methods that participants must use. Participants must be informed of this requirement prior to joining the scheme.**

  e.g. *"Laboratories will be expected to process samples in the same way as a sample would normally be processed in their laboratory so that the testing process reflects the day-to-day functions of the laboratory."*

- **Plan the statistical analysis that will be used**
- e.g. "*Outliers for all sample results will be detected using Grubbs' test. The mean and SD for each sample (by assay) will be calculated after removing outliers using Grubbs test ($p<0.05$). A Z-score will then be calculated for each sample result using this trimmed*



Describe what reports and data will be returned to participants

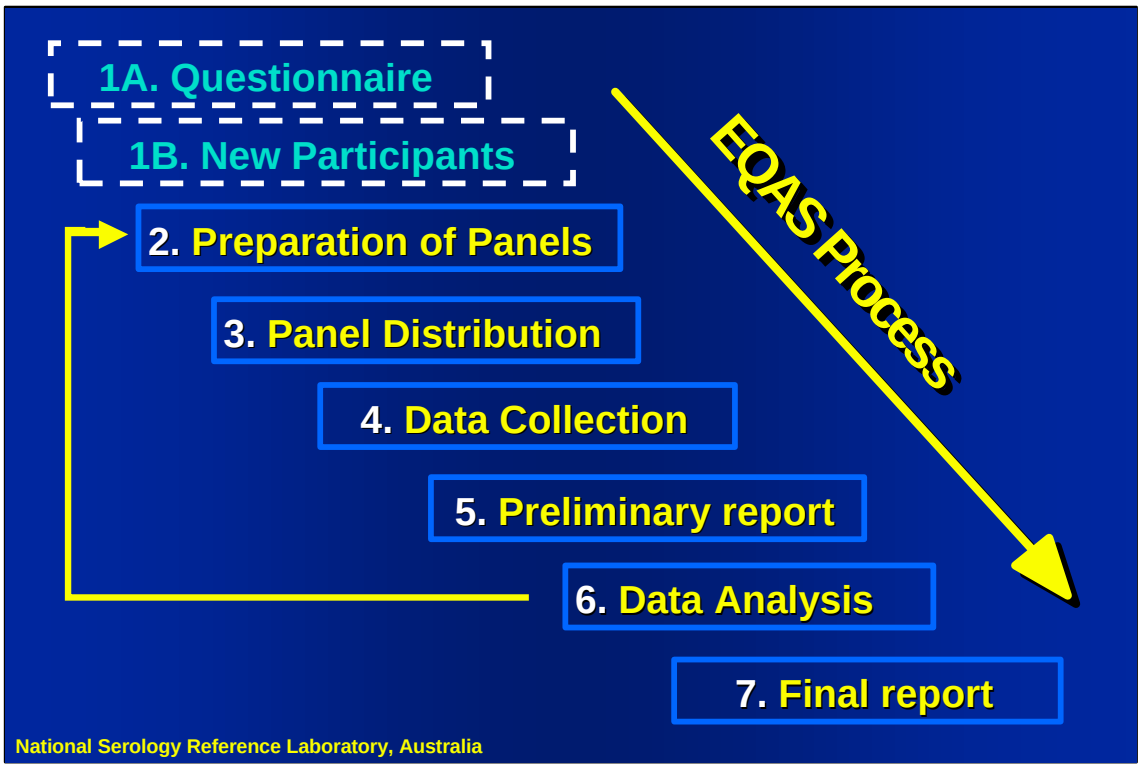
E.g. *"The returned data will then be analysed to identify any aberrant or significantly different results. This analysis will then be discussed in a final report which will be sent to each laboratory as quickly as possible."*

- **Document how the performance of laboratories will be evaluated**

  E.g. Decide whether test results will be analysed to identify outlying results or whether the performance will be assessed on the anti-HIV status reported only.

- **Decide if results and conclusions will be made public**

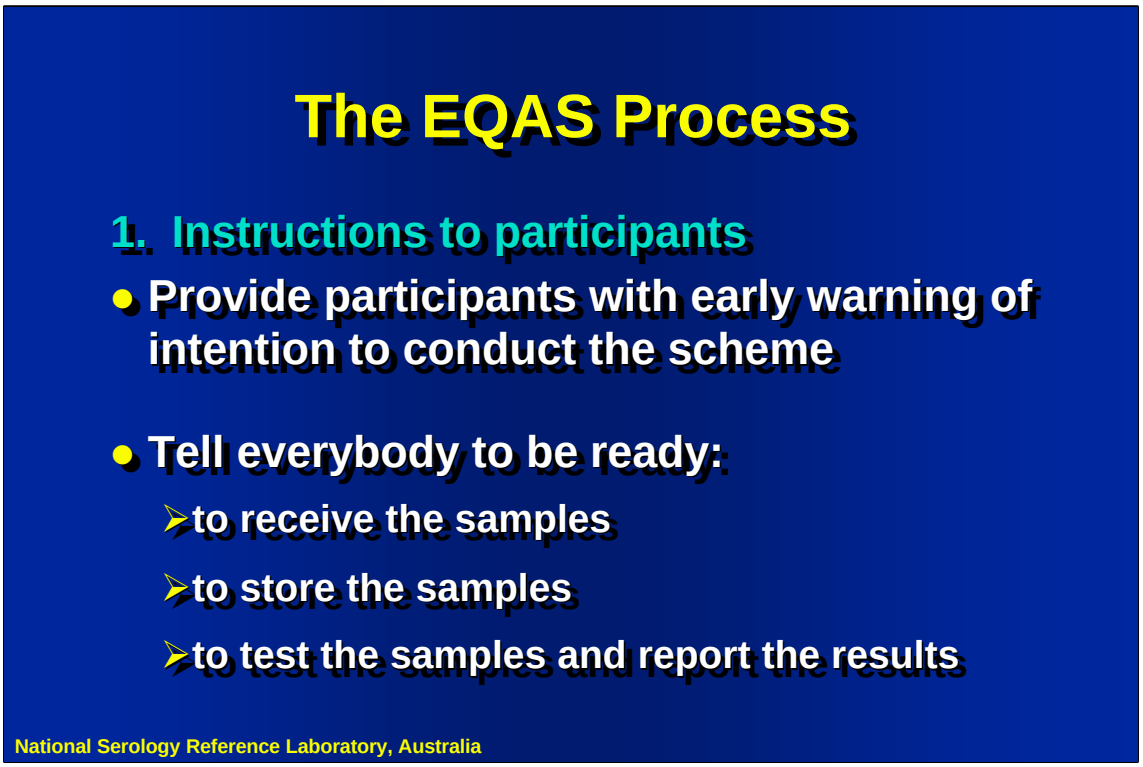
Usually identify all laboratories by a code number at all times. This code number should not be given to anybody else at any time.



The EQAS process

Now that we have planned our EQAS I will move on to discuss issues at each step of the EQAS process.

1. Setting up an EQAS



Adequate instructions need to be provided to participants so that they can participate as easily and as correctly as possible.

Because the NRL runs an ongoing EQAS we send a letter to each participant at the start of each year detailing:

•when the panels will be distributed,

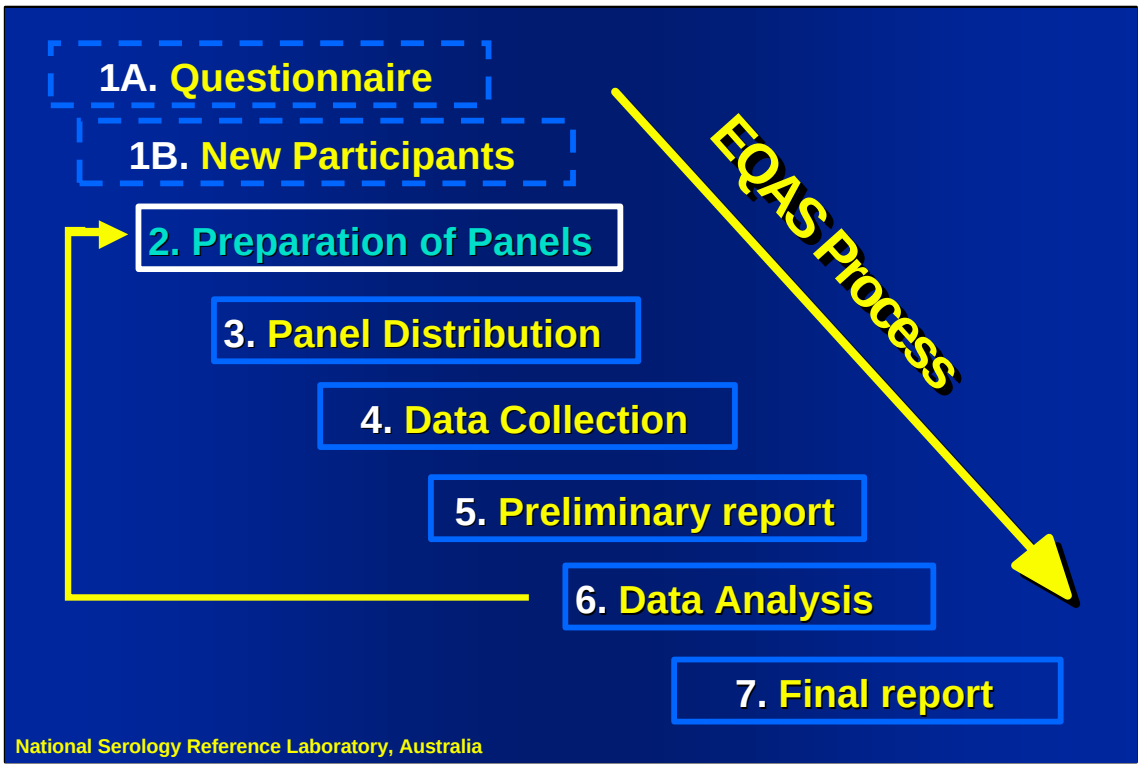
•what type of samples the the panels will include e.g. plasma or whole blood,

•how to store the samples when they are received,

•what testing procedures should be used (follow routine testing strategies),

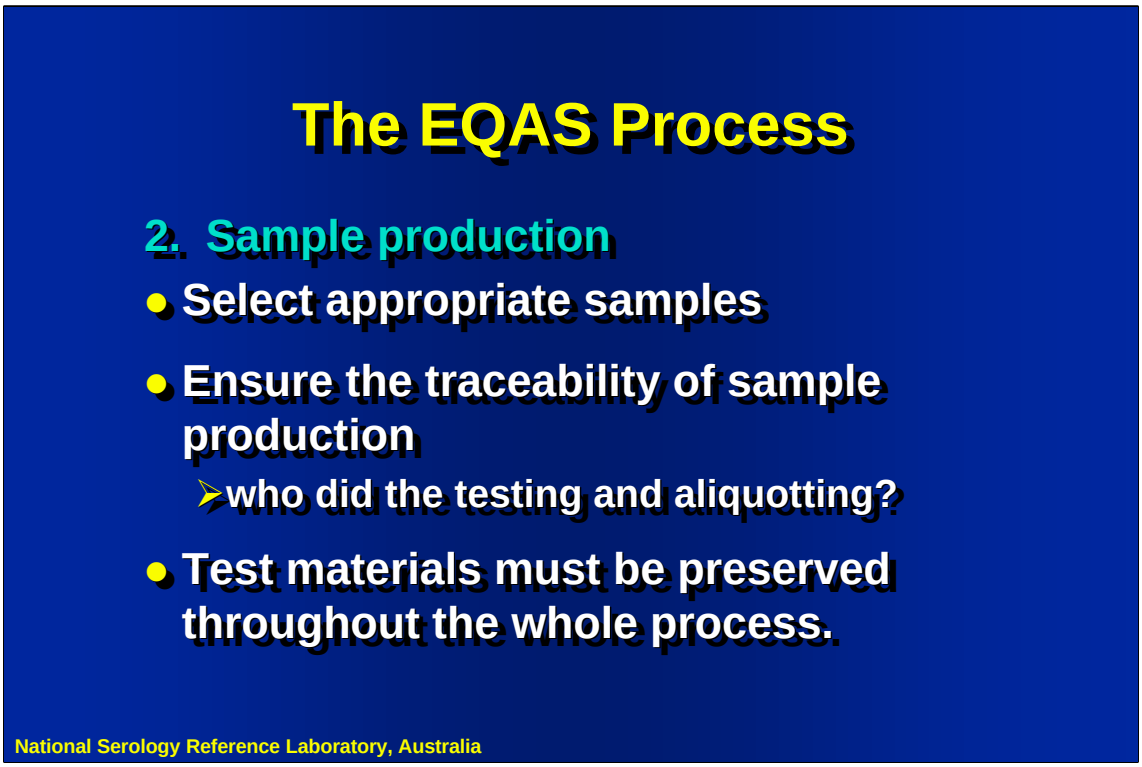
•how long participants have to return results if they are to be analysed and included in the report (e.g. 30 days from receipt of samples),

•how results should be returned (e.g. mail or fax the hard copy forms).



The EQAS process

2. Sample production



2. Sample production

EQAS samples must be of good quality so that any problems can be attributed to the testing process in the participating laboratory and not poor sample quality. Poor results due to poor quality samples will lead to a lack of confidence in the EQAS results.

Select appropriate samples

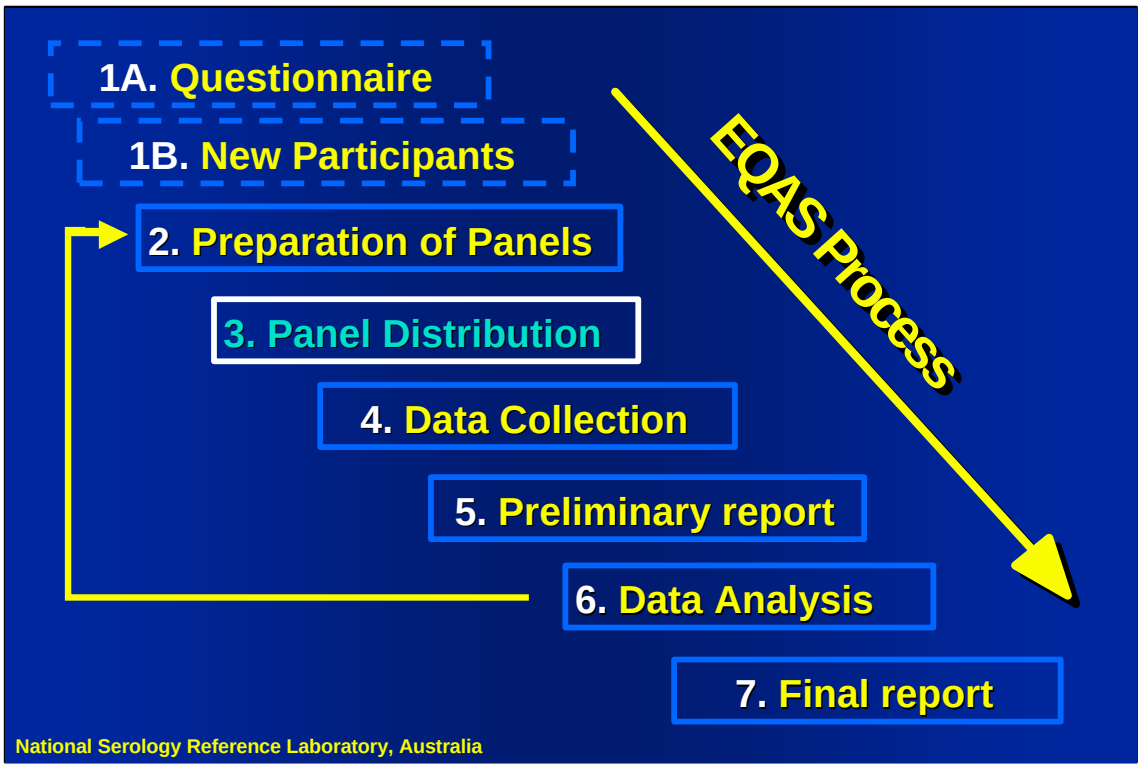
Samples should be selected for the types of tests and testing performed by the participants.

Ensure the traceability of sample production

Make forms or checklists for recording who performed each task in setting up the panel. E.g. who aliquotted each sample. Each step should be signed off. These forms act as a reminder to complete the process in full and to ensure all aspects of the sample production process are traceable. If any problems occur the EQAS provider should be able to trace where the problem occurred so that it can be fixed.

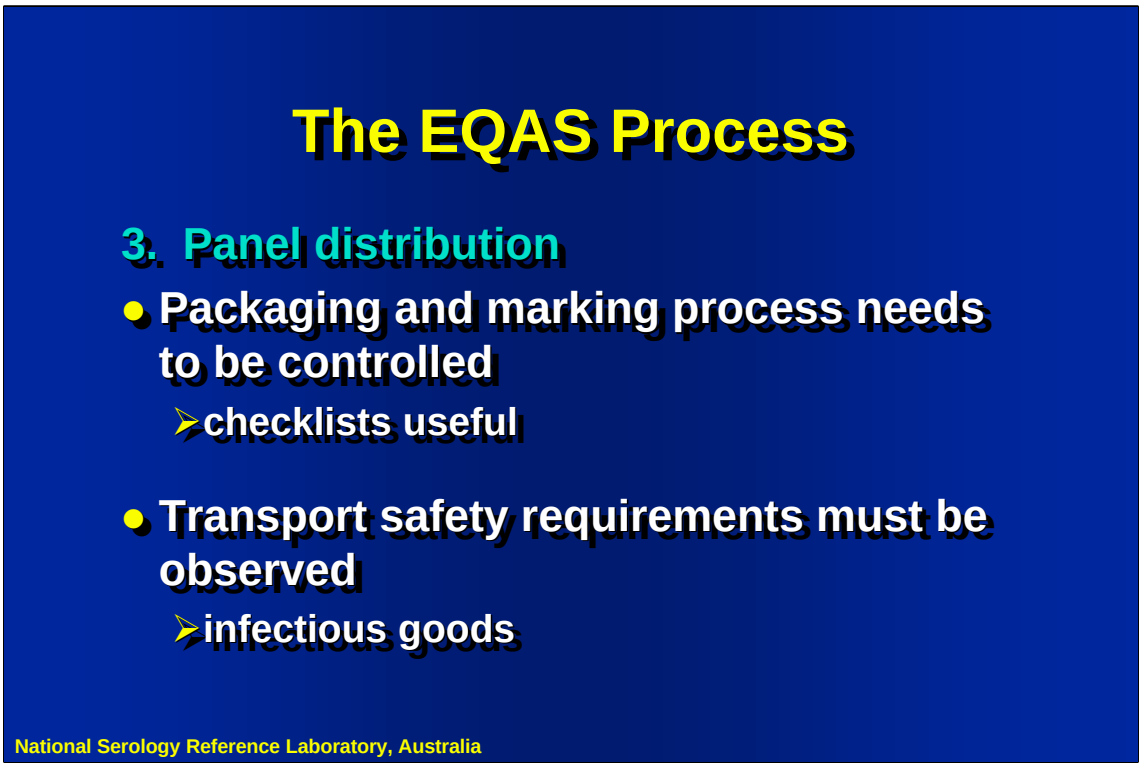
Preservation of test materials

There must be mechanisms in place to preserve the panel specimens. For example, **keep plasma or serum at 4ºC** between preparation and distribution. Ensure that the time that samples spend at ambient temperature is minimised.



The EQAS process

3. Panel Distribution



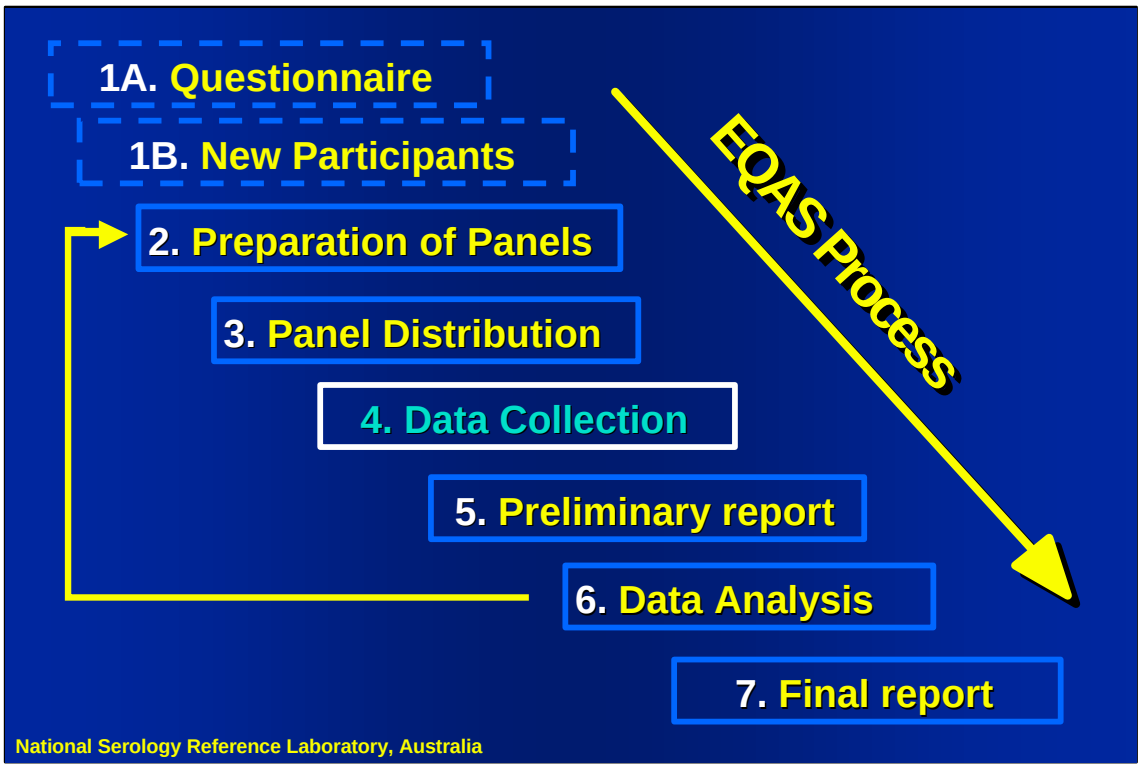
3. Panel distribution

Ensure that the packaging and labelling process is of a high standard. Keep in mind that this is the point where the samples leave your care but are at their most vulnerable.

Checklist are useful to ensure the traceability of each step. Each staff member should sign off when they have completed a task such as aliquotting.

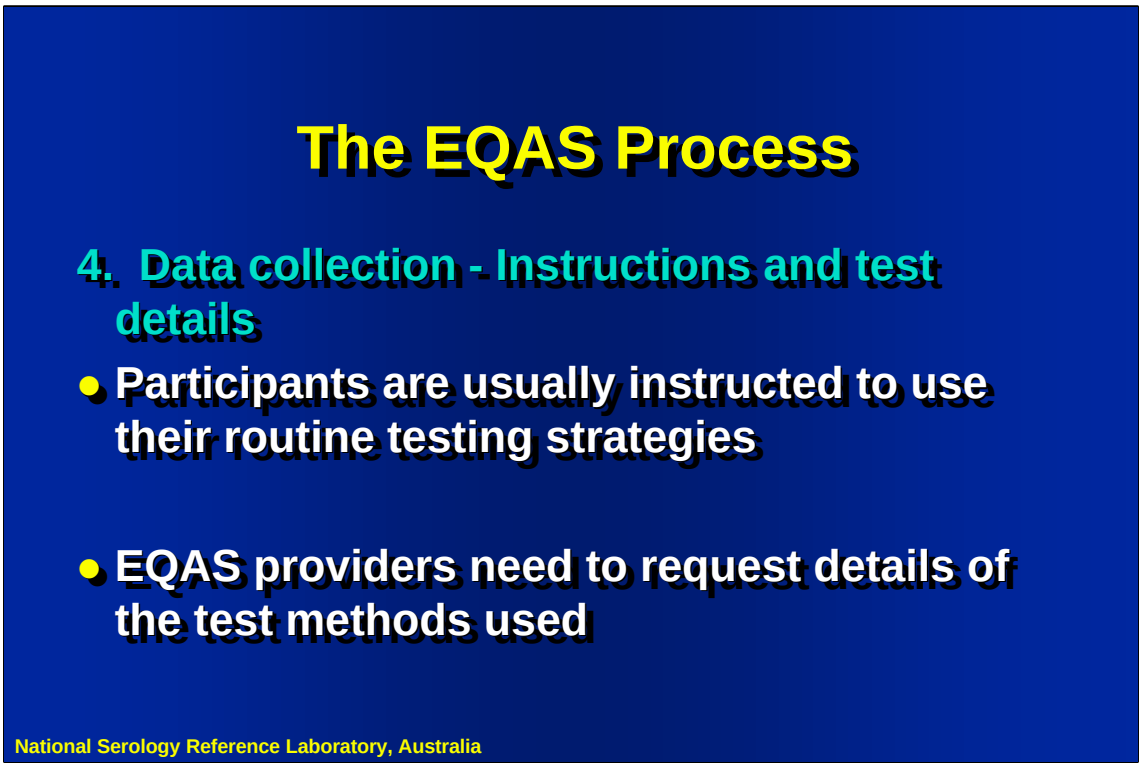
Tube labels must be securely attached - buy good quality labels that will stay attached over a wide temperature range or test them before use. Labels on tubes and packaging should be of high enough quality to remain legible within the period of use of the scheme.

National and/or international safety and transport requirements must be followed. There are detailed international regulations for transporting infectious goods. Keep in mind that the samples you are distributing contain the HIV virus and the samples should be packaged to avoid leakage.



The EQAS process

4. Data collection



4. Data collection

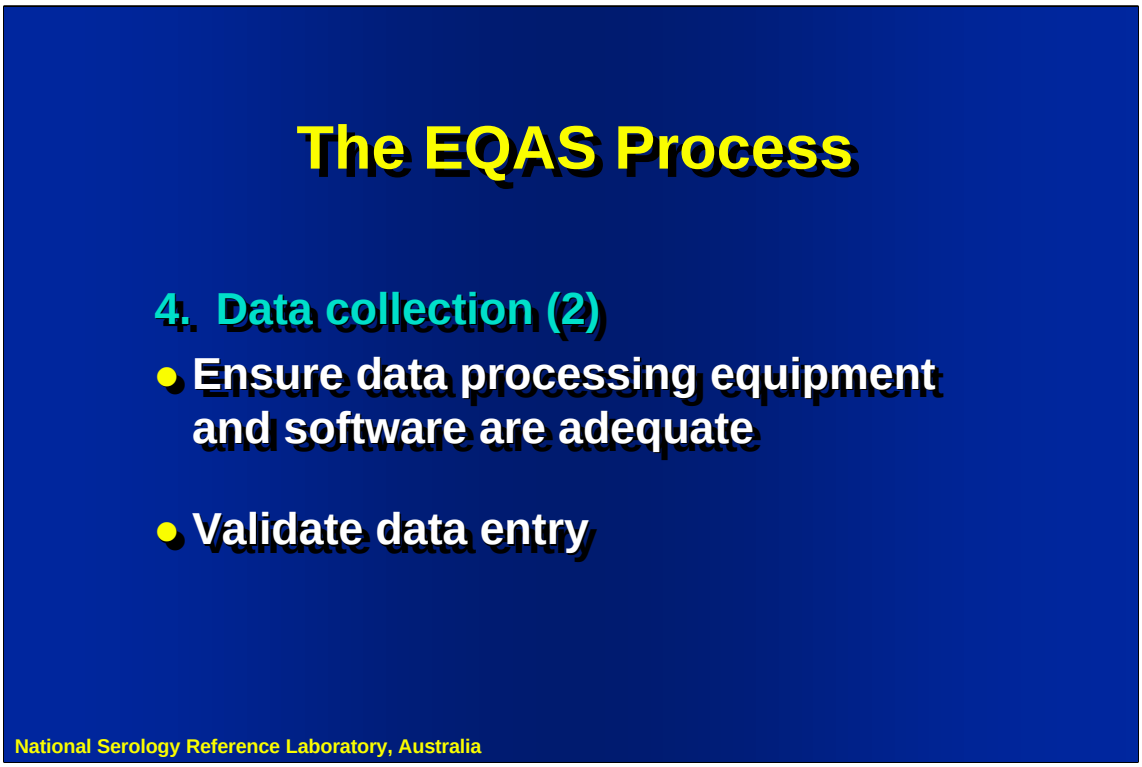
Participants are usually instructed to use their routine testing strategy because the point of an EQAS is to assess the testing process.

Make the return of results as easy as possible for the participants.

Use a specific form for the return of results to obtain the:

- full name of assay (catalogue no.) and manufacturer
- kit batch number
- date
- expiry date
- operator
- results
- test interpretation
- final status interpretation

A form that is easy to fill out correctly will ensure that results returned for the same assays can be compared and assessed.



4. Data collection (2)

It is important for the quality of the analysis and the reports that the data processing equipment and software are adequate

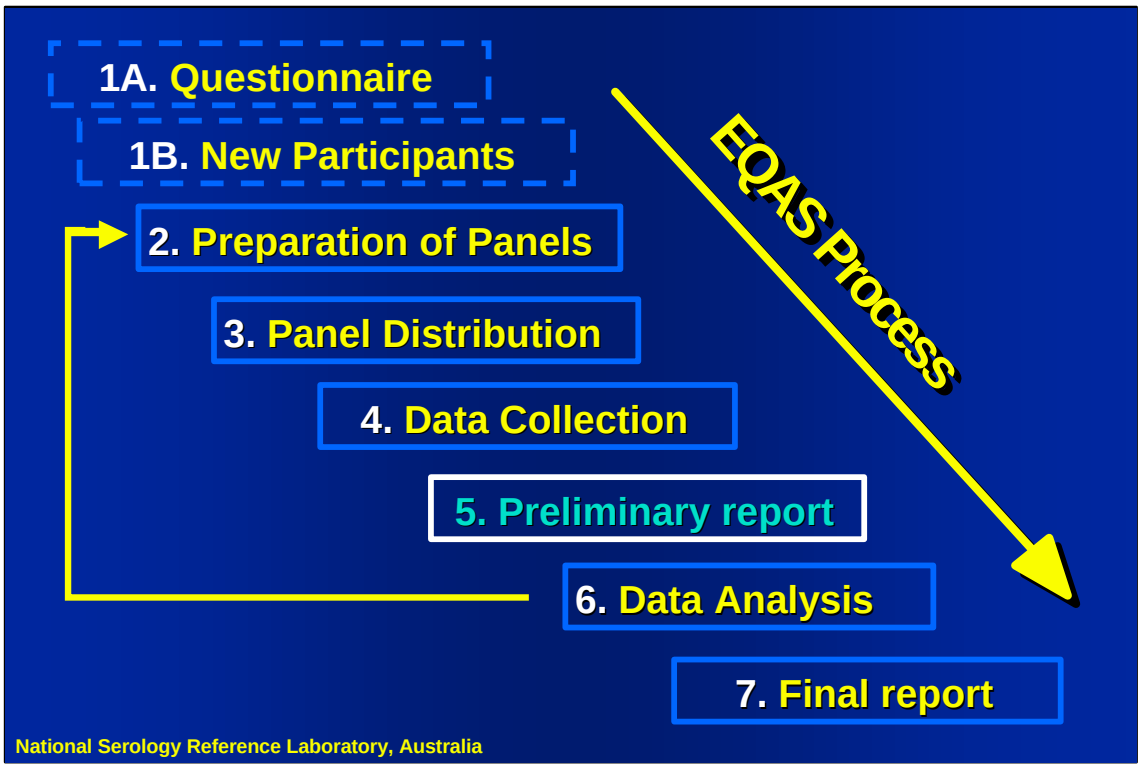
Data processing equipment must be adequate for all data entry and statistical analysis. It must be capable of timely and valid results.

The EQAS provider should designate people to be responsible for effective data entry and analysis.

If software is available, it should be backed-up and have a system recovery plan.

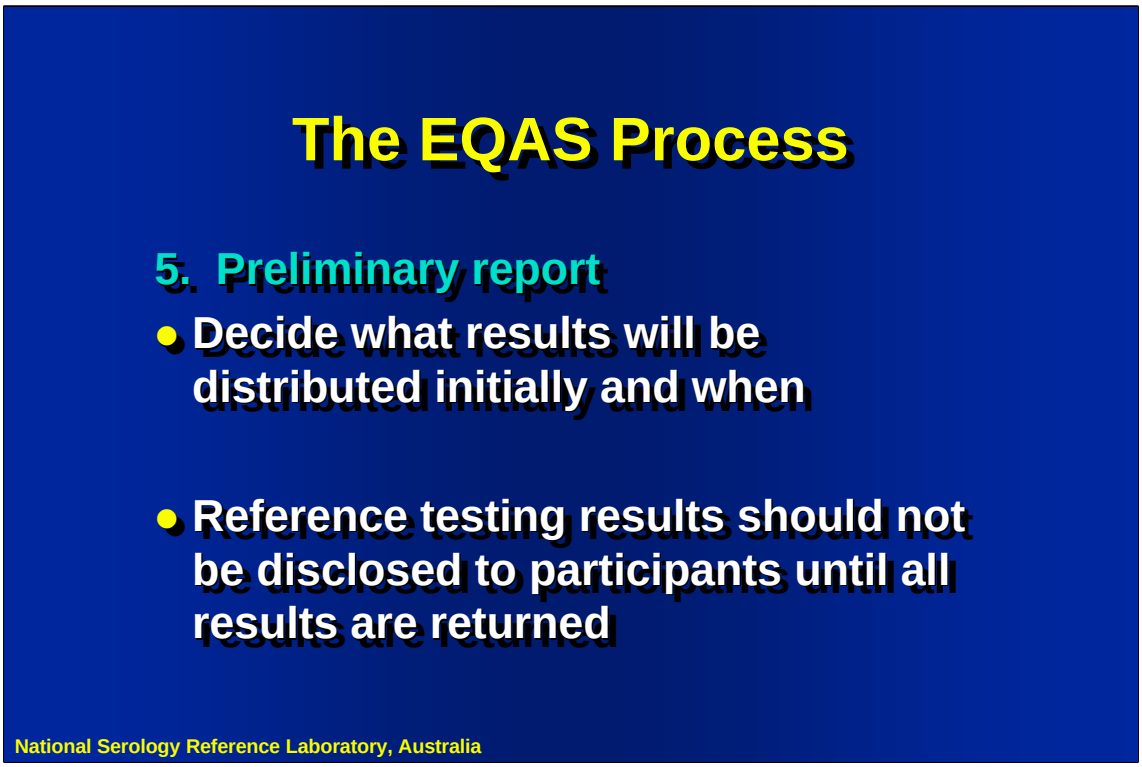
The quality of the data will be ensured by validating the data entry

Print out the entered results and compare this with the original data returned by participants. Have a person who did not do the data entry check the results and make any corrections.



The EQAS process

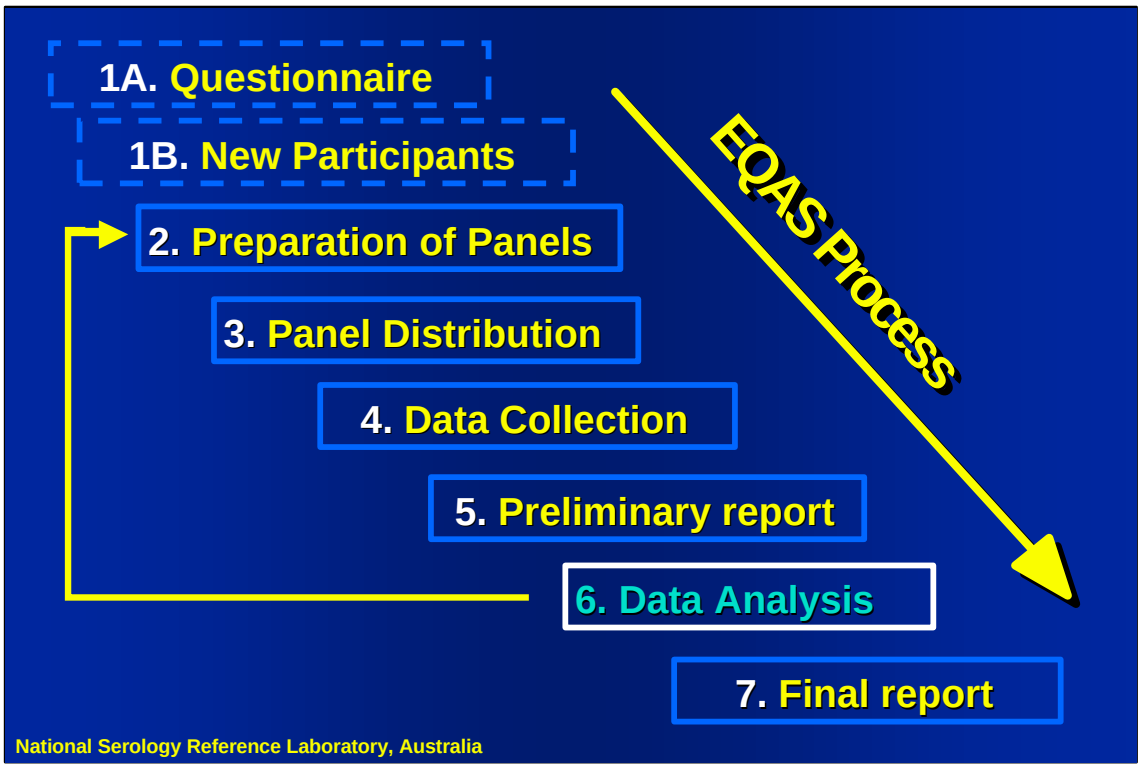
5. Preliminary report



5. Preliminary report

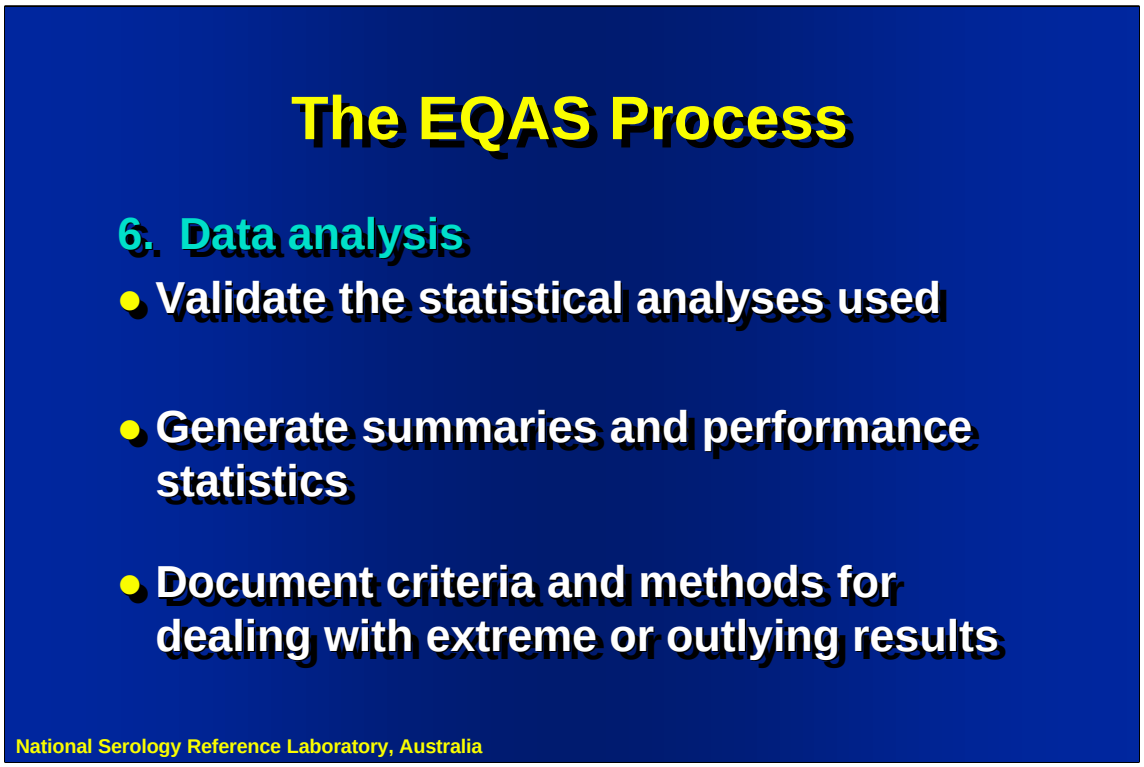
Decide what results will be distributed initially and when. A quality EQAS will provide the participants with some feedback as soon as possible so that errors can be followed up quickly. The easiest way to do this is to distribute the reference results once all the results are received.

ILAC-G13:2000 states that reference testing results should not be disclosed to participants until all results are returned. To comply with this requirement the NRL does not return the reference results initially and sets a firm deadline for accepting results so that the report can be distributed in a timely manner.



The EQAS process

6. Data analysis



6. Data analysis

Validate your statistical analyses

Test small numbers of data and compare your analytical method with what you get when using a calculator.

E.g. 1, 2, 3, 4, 5

Mean = 3 and SD = 1.58 in Microsoft Excel and by calculator. Keep a record of this validation, date and staff member initials.

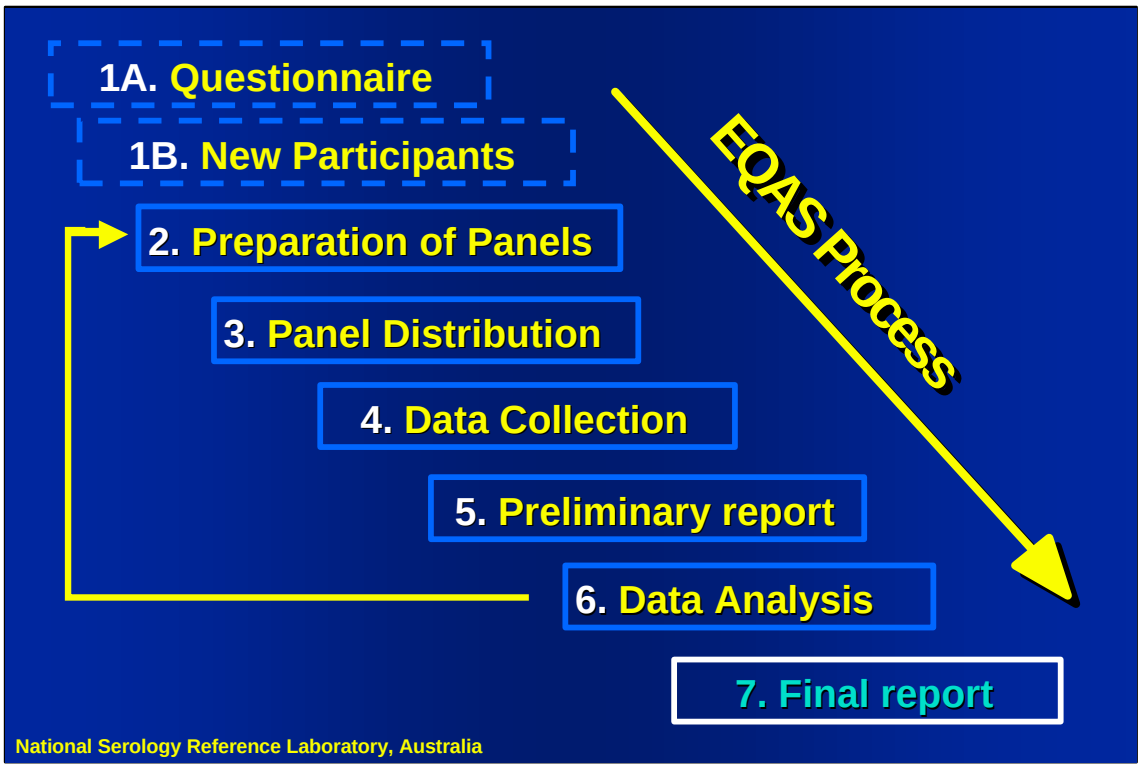
Generate summaries and performance statistics

Ensure that the summaries and performance statistics are consistent with the overall model and objectives of the scheme. The statistics used should be **<u>useful</u>** to the participants.

Use appropriate statistical tests to minimise the effect of outliers. Robust statistics are the most common method used for this purpose.

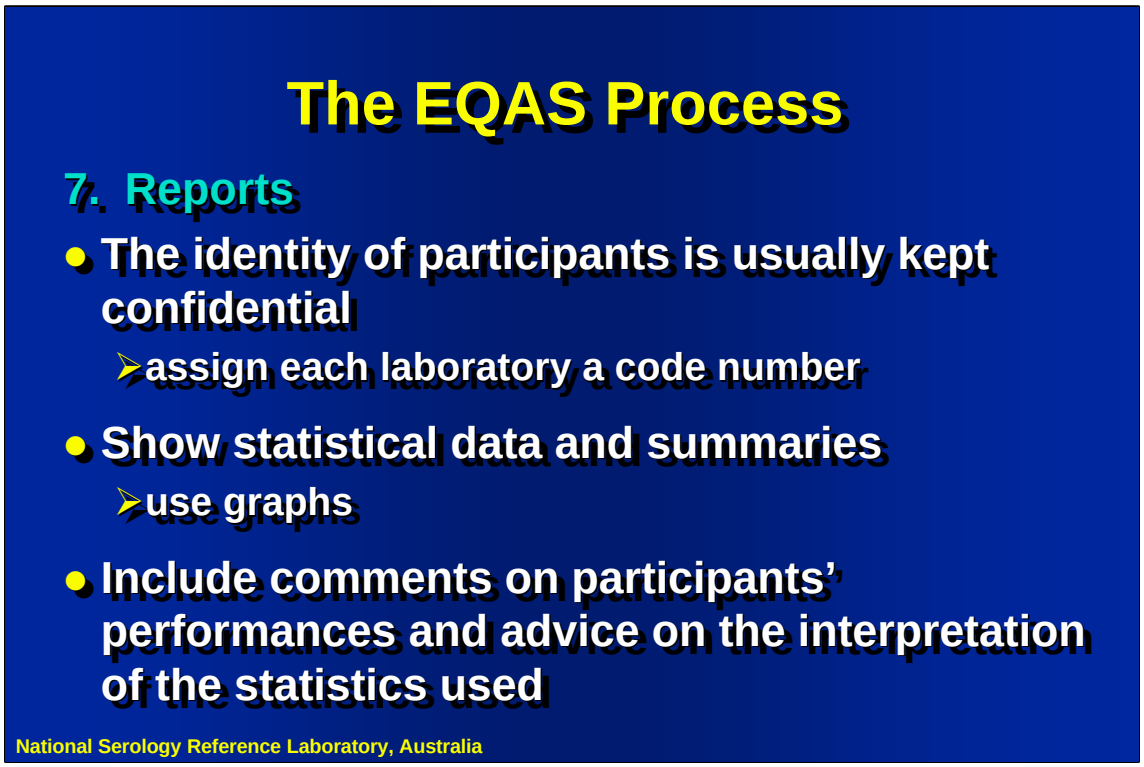
Extreme or outlying results (gross errors, miscalculations or transcription errors) can severely influence the summary statistics. Minimised this influence through documented criteria for dealing with obvious mistakes.

E.g. *"Obvious mistakes (such as miscalculations or transcription errors) can drastically affect the summary statistics. These obvious mistakes may be removed at the discretion of the co-ordinator but must be commented on in the report."*



The EQAS process

7. The Final Report is the most important element of the EQAS because it is the feedback to the participants. It is very important that the report is clear and easy to understand.



7. Reports

Confidentiality

The identity of participants should only be known to the scheme organisers and should never be given out to anyone. Give each laboratory a code number that can be used in all reports. This will encourage participants to report honest results and will discourage the misuse of EQAS reports by third parties.

Final Reports

Content can vary but the report must be clear and comprehensive.

Use graphs to summarise the data.

Show all the data if possible. However, the report must include information on the statistical distribution of results from all participants together with an indication of the performance of individual participants.

Report would normally include:

•name and address of the provider and co-ordinator(s)

•date the report was issued

•report number and name of the scheme

•description of the samples used and how they were prepared

•laboratory codes and test results

•statistical summaries and graphs (usually grouped into assay names)

•comments on the performance of the participants

I will now discuss the international standards for Quality Management -ISO 9000

They are standards for quality management and quality documentation.

They are broad standards that can be applied to any organisation.

ISO 9001:2000 is a newer (updated) version that puts more emphasis on business processes such as measuring customer feedback.

ISO = International Organisation for Standardization

Management system requirements

To have a good quality organisation there are management system requirements that can be guided by ISO 9001.

Some of these requirements include:

Corrective Actions

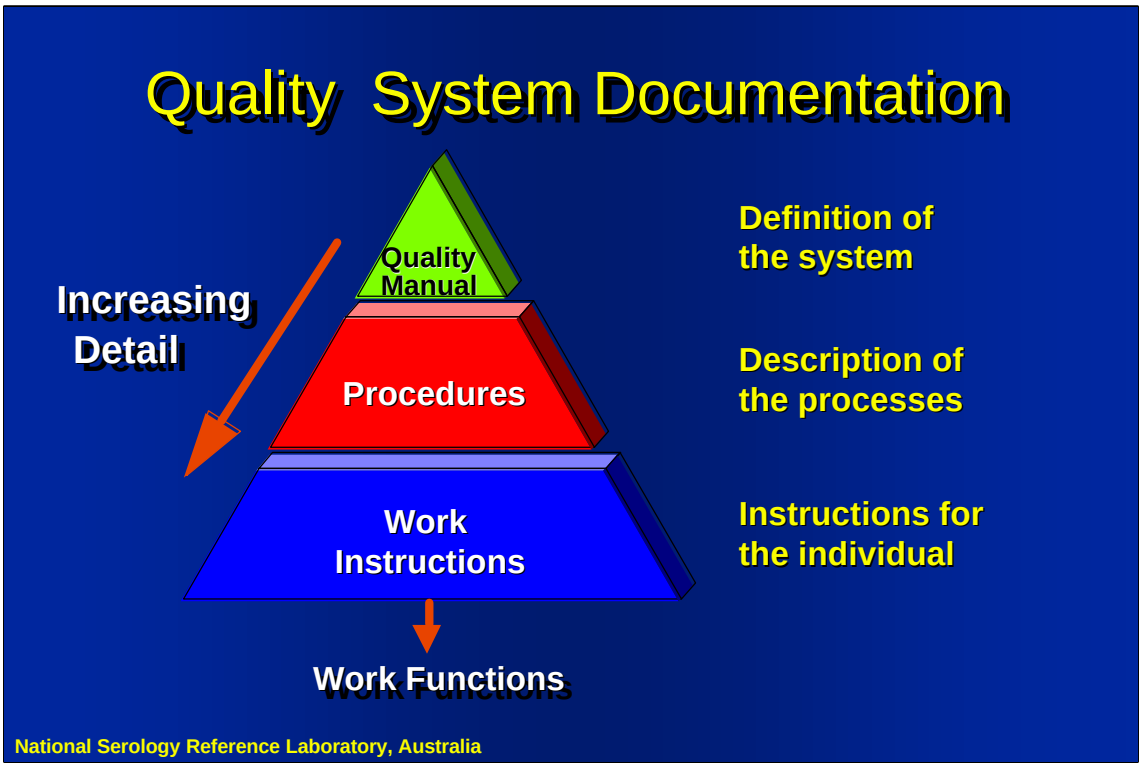
Take actions to correct a problem (such as an incorrect result or a departure from procedure) so that the organisation can continually improve quality.

Internal Audits

Run regular systematic and independent examinations of the quality management system by someone within the organisation. Check that all staff are following the Work Instructions.

Document Review

Ensure all documents are subject to regular review by competent staff to keep them up to date.



Quality system documentation

There are no rules about how the documentation is structured but this is how we structure our documentation at NRL.

Quality Manual = Company Policy & System outline. The quality manual is a guide to the rest of the QMS documentation.

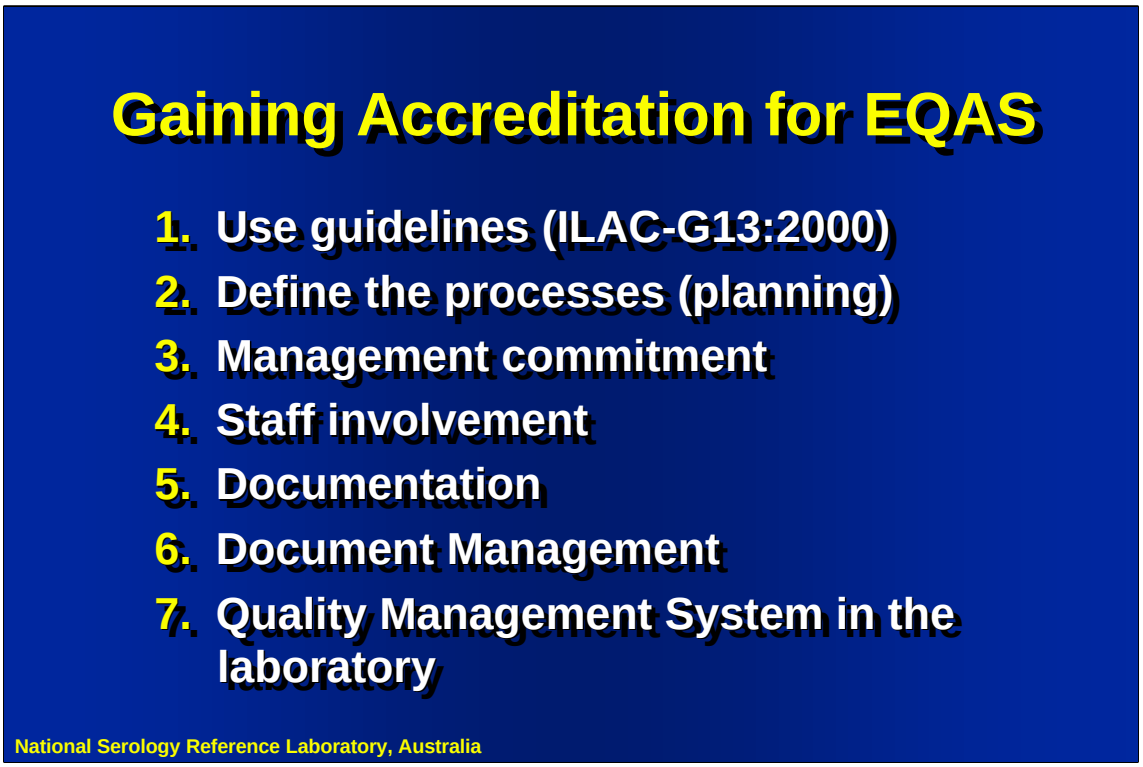
•Outline the structure of the rest of the documentation. You do NOT have to use the term “Quality Manual”

Procedures = Define how the policy is carried out in individual work areas e.g.describe the overall procedure for your EQA programme such as who is responsible for carrying out the reference testing.

Contain sections on:

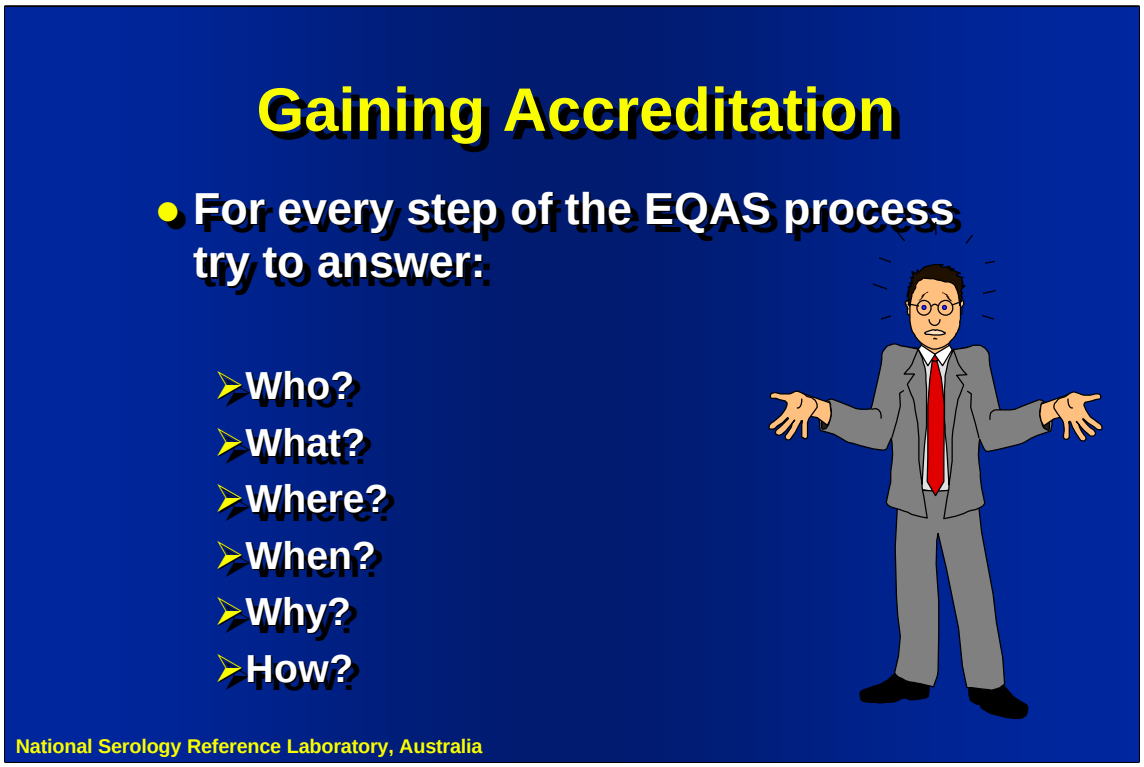
- •Purpose of the procedure
- •Scope
- •Method
- •Records
- •Documents such as individual Work Instructions

Work Instructions = Specific instructions for individual tasks e.g. how to aliquot EQAS samples or perform a laboratory test method.



If you are hoping to gain accreditation for EQAS:

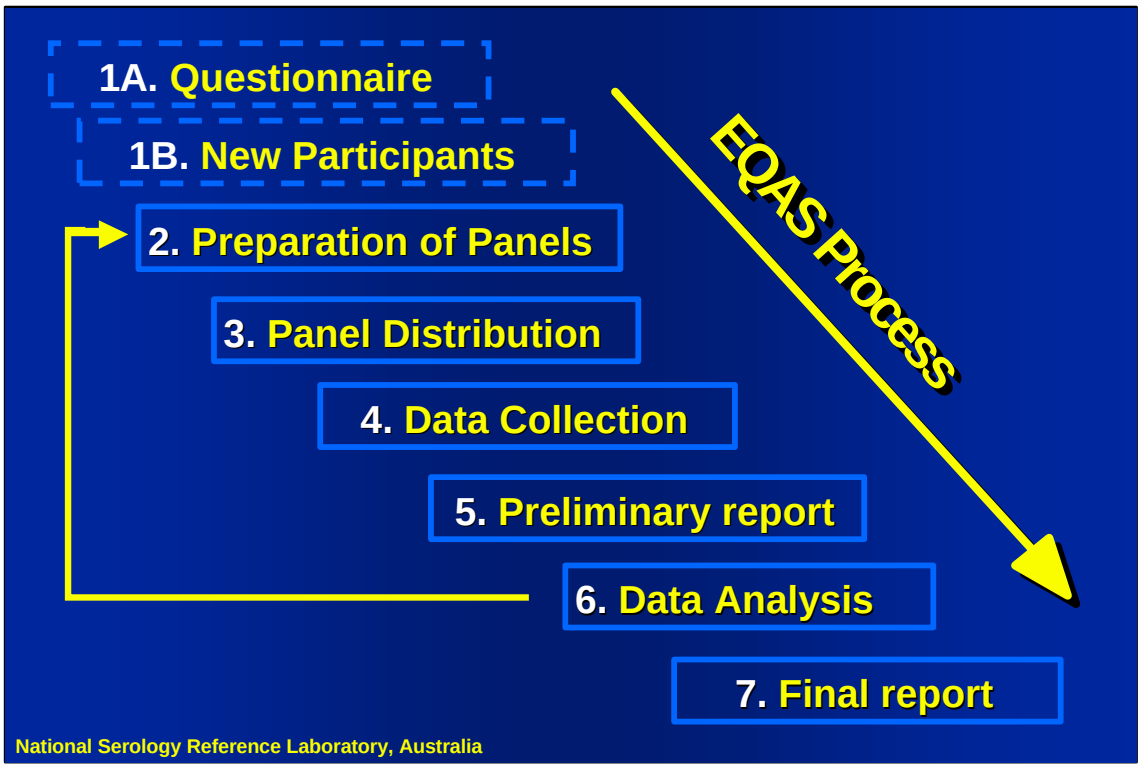
1. Use ILAC-G13:2000 to help you find areas that can be improved
2. Define the areas that are most important and plan what needs to be done.
3. Management must be fully committed as time and resources will be required, especially in the initial stages.
4. Select staff to be responsible for each part of the process.
5. Write the quality documents (Quality manual, procedures and work instructions)
6. Devise a system to control the documents. Any changes must be reviewed and authorised prior to updating.
7. Use ISO 9001 or relevant parts of ILAC-G13:2000 as as guide to improve the Quality Management System in the laboratory.



Gaining accreditation

As I said earlier, if you can answer (**and document**) the questions for every step of the EQAS process you are well on your way to developing a quality EQAS.

PTO



The EQAS process

Gaining Accreditation. Ensure quality of every step of the process

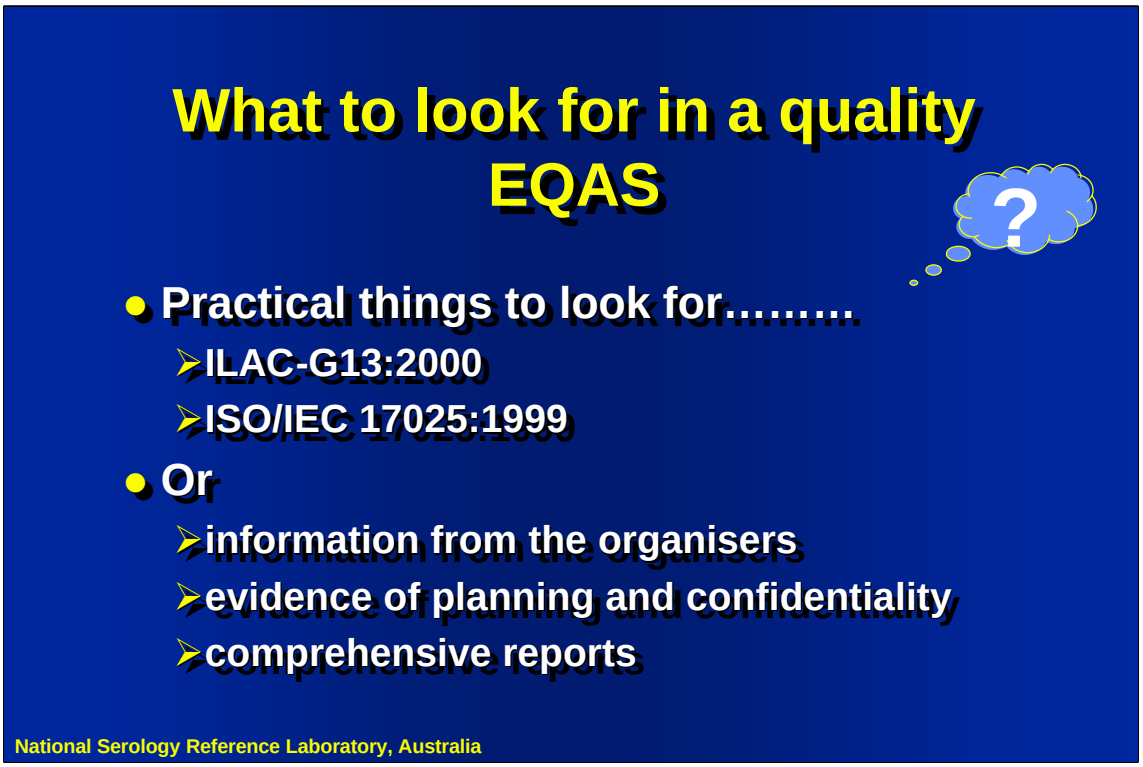
Take sample production for EQAS panels as an example:

- **Who** is responsible for co-ordinating the sample selection, testing and production?
- **What** testing should be done to characterise the samples?
- **What** company will be used to ship the samples to participating laboratories?
- **What** paperwork will be included with the samples?
- **What** type of samples will be selected (and who will do this)?
- **Where** will the testing be done (and by whom)?
- **Where** will the aliquotting of samples into smaller volumes be done (and by whom)?
- **When** do the samples need to be shipped out?
- **Why** is the panel being sent out? For example, why send a majority of HIV subtype B positive samples when the majority of infections in the country are due to subtype E?
- **How** much volume of each sample will we need?
- **How** will samples be packaged for shipping?

Quality management is a journey……. not a destination

In other words:

Organisations should be striving for continual improvements to their Quality Management System.



What to look for in a quality EQAS

Some of you may not be able to provide an EQAS scheme but will want to participate in somebody else's scheme.

Laboratories looking for a quality EQA scheme to participate in should find out if the organisers are **accredited to some well recognised guidelines** (such as ILAC-G13:2000 or ISO/IEC 17025:1999). Even if the EQAS provider is not accredited, ask if they follow any international guidelines.

Failing this, laboratories should ask for:

•Information from the providers of the scheme

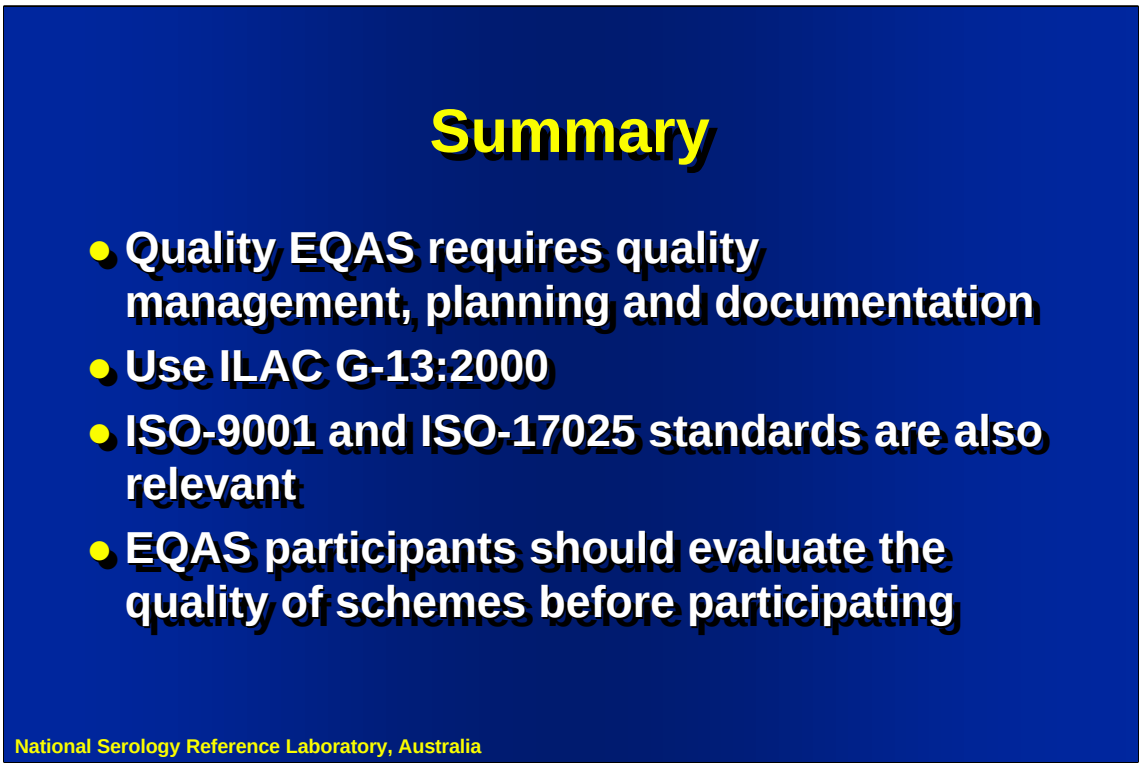
•Confirm that the provider knows when panels will be distributed and what type of specimens they will be.

•Evidence of planning and confidentiality

•Before a laboratory participates in an EQAS, they should ask the organisers for information about the scheme and whether your laboratory will be identified to anyone else.

•Comprehensive reports

•Ask the organisers of the scheme to provide you with a ***copy of the previous report.*** Look for a good explanation of the statistics used and good summary



Summary

Quality EQAS requires quality management, planning and documentation

International standards and guidelines can be used to improve the quality of your processes. ILAC-G13:2000 is an international guideline that is specific for EQAS providers.

ISO9001:2000 and ISO-17025 standards are also relevant for improving the quality of management and the laboratory.

EQAS participants should evaluate the quality of schemes before participating. Use what you have learnt at this workshop to ask some basic questions about the processes involved.

REFERENCES

Libeer, J.C. *et al*. Characterisation and classification of external quality assessment schemes (EQA) according to objectives such as evaluation of method and participant bias and standard deviation. *Eur J Clin Chem Biochem* 1996; 34:665-678.

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