



QAP MATERIAL DEVELOPMENT



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QAP Material Development

- General Chemistry Diluent Pilot Study
- Troponin I Replacement Vial



General Serum Chemistry Diluent Pilot Study 2010

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General Chemistry Diluent Pilot Study

Current Status

- Lyophilised vial
- Diluent vial





General Chemistry Diluent Pilot Study

- Diluent vial - contains sodium bicarbonate as the bicarbonate is unable to be stabilised in the lyophilised material
- Manufactured to provide a linear range of levels



General Chemistry Diluent Pilot Study

- Aalto Scientific manufactured pilot vials of a new formulation of the General Serum Chemistry material
- This formulation had the bicarbonate stabilised in the lyophilised vial
- They requested the assistance of the RCPA Chemical Pathology QAP in the evaluation of the new formulation



General Chemistry Diluent Pilot Study

- Pilot vials were provided by Aalto Scientific free of charge
- 4 levels
- ? Any interferences or biases on any of the major systems that RCPA QAP's participants use



Study Design

Material despatched to 16 laboratories with a variety of instrumentation



Laboratory's assay for all analytes that they currently submit results for in the General Serum Chemistry Program



Assayed on two consecutive days



Instrumentation

Abbott Architect c4000/c16000	1	Osmometer Fiske	1
Abbott Architect c8000	1	Roche Cobas c501	1
Abbott Architect i2000-i8000	2	Roche Cobas Integra 400/400+	1
Abbott AxSYM/AxSYM+	1	Roche Cobas Integra 700/800	1
Beckman Coulter Access/Access 2/DxC 600i Immunoassay only	1	Roche E170/e 601	3
Beckman Coulter UniCel DxC 600/600i Chemistry Only	1	Roche Elecsys 1010/2010/Cobas e 411	1
Beckman Coulter UniCel DxC 800	1	Roche Hitachi Modular	3
Beckman Coulter UniCel Dxl 600/800	1	Siemens Advia 2400	2
OCD VITROS 5,1 FS/5600 (c)	2	Siemens Advia Centaur	2
Olympus AU2700/AU5421/AU5432	1	Siemens Dimension XL/RXL/RXL MAX	1
Olympus AU600/640/680	1	Siemens Immulite 2000	1
Osmometer Advanced	4	Siemens Stratus CS	1

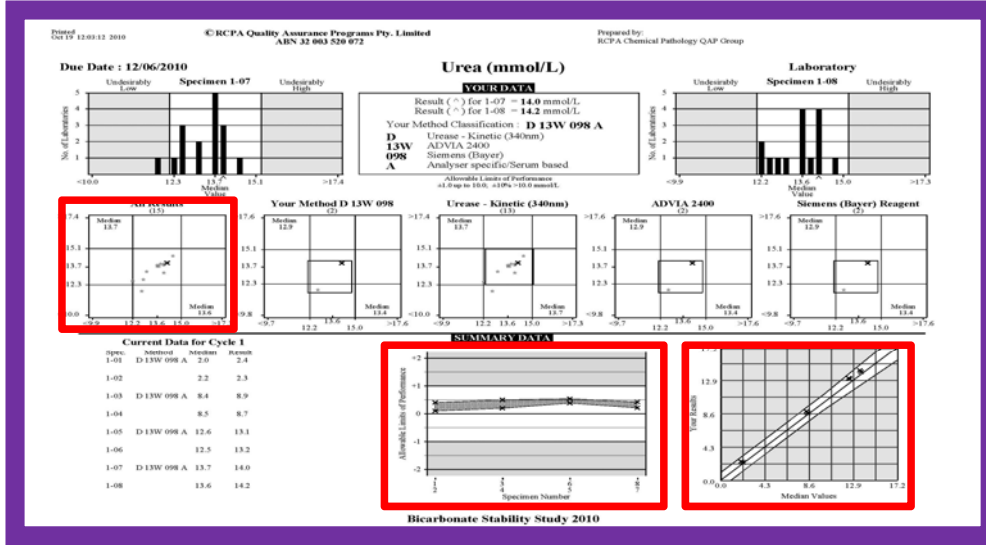


Method

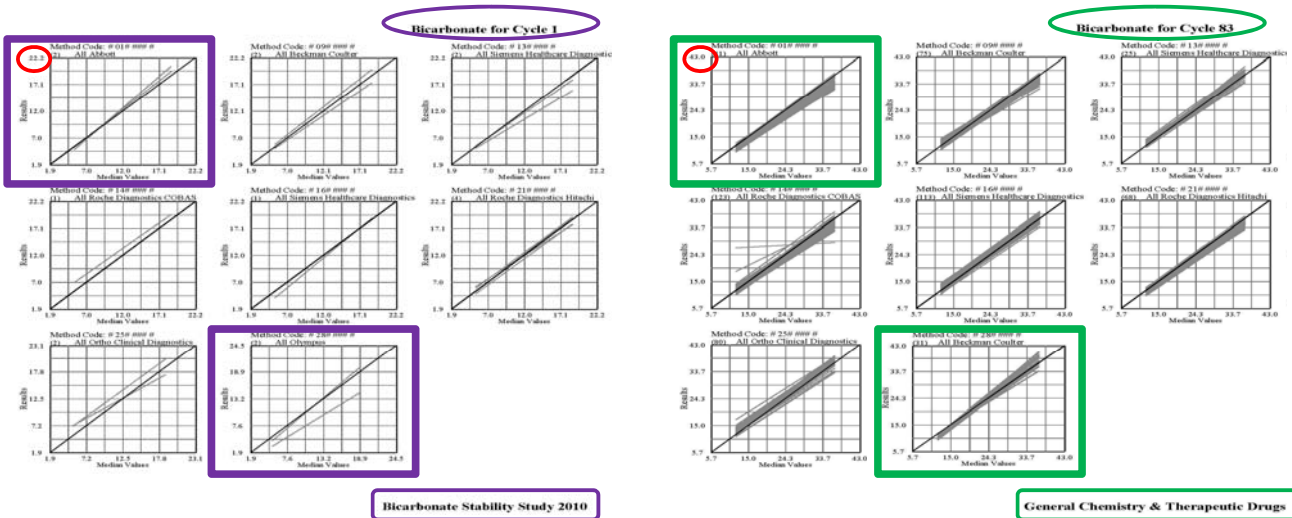
- Set up as an RCPA Program
- Allowed review of:
 - precision
 - linearity
 - method bias
 - comparison to current material



Results



Results - Bicarbonate

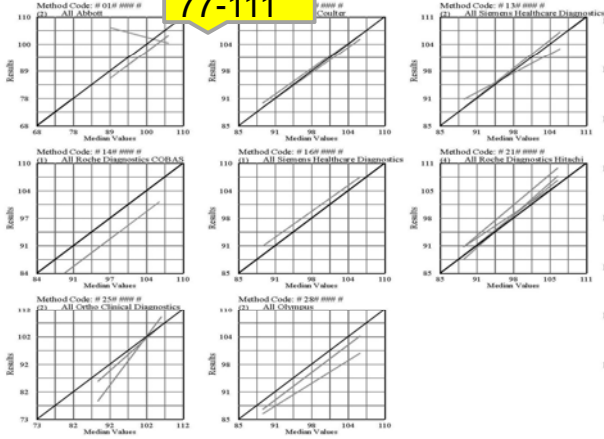




Results - Sodium

Range
77-111

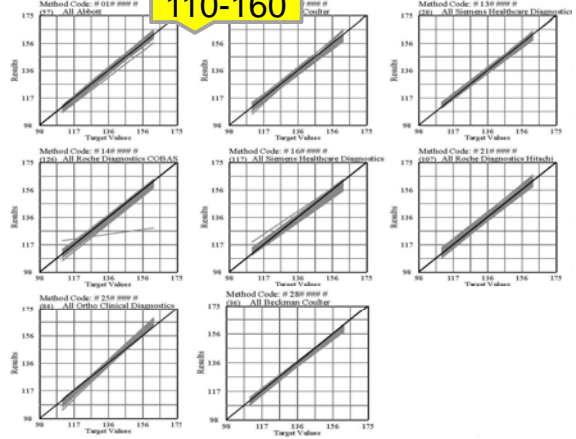
Sodium for Cycle 1



Bicarbonate Stability Study 2010

Range
110-160

Sodium for Cycle 83

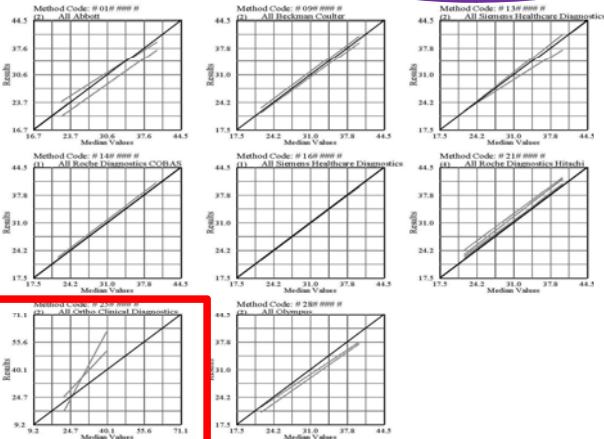


General Chemistry & Therapeutic Drugs



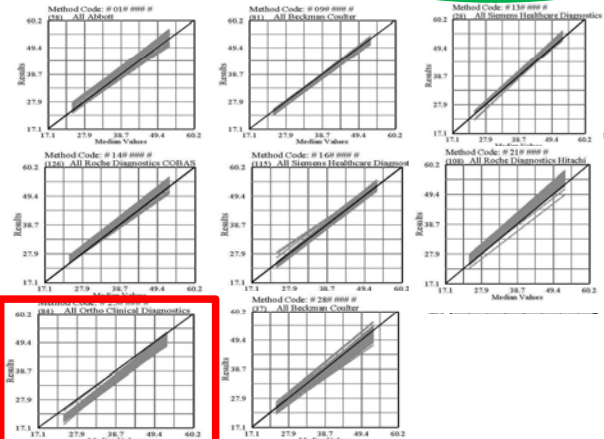
Results - Albumin

Albumin for Cycle 1



Bicarbonate Stability Study 2010

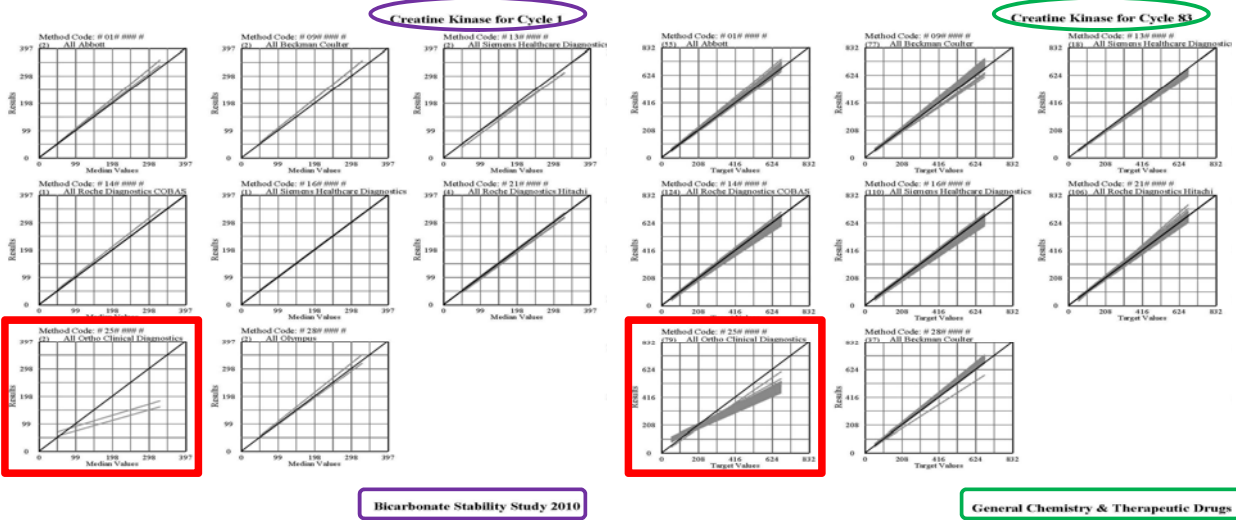
Albumin for Cycle 83



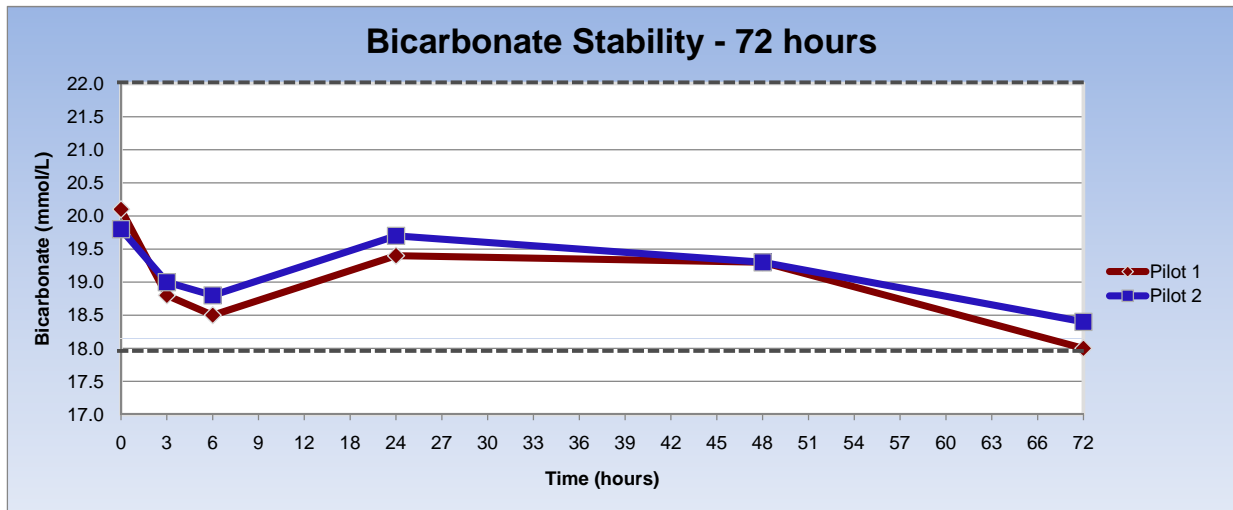
General Chemistry & Therapeutic Drugs



Results – Creatine Kinase

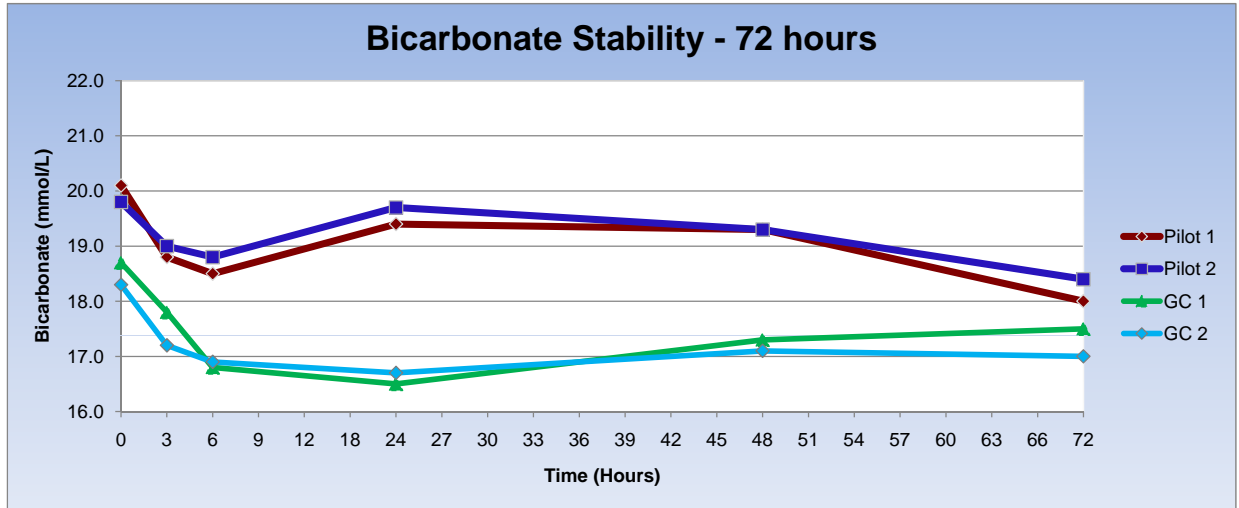


Bicarbonate Stability

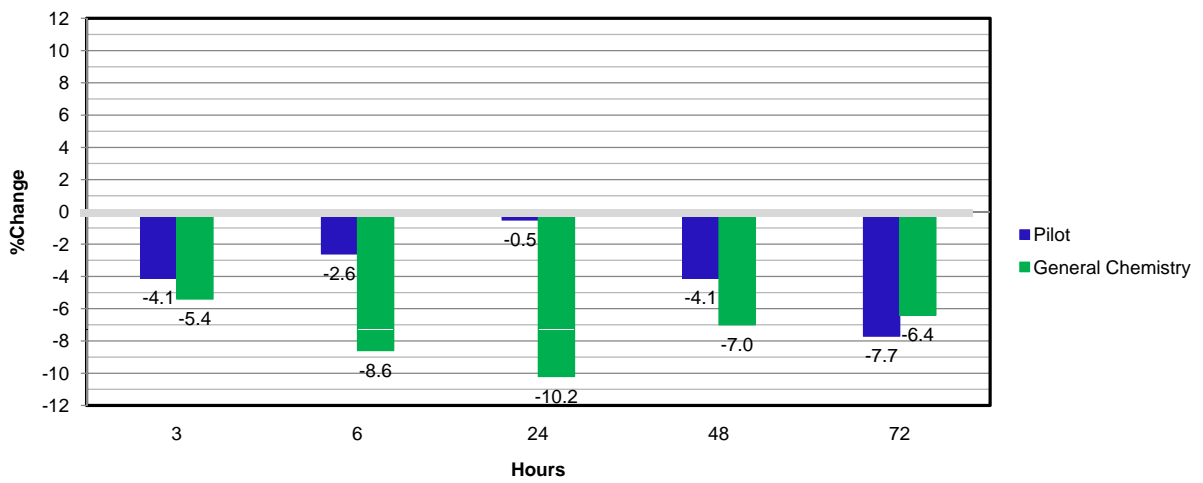




Bicarbonate Stability Comparison



Bicarbonate Stability % Change





Summary

- Linear response
- No obvious interferences with the new material
- Some instrument biases noted



Discussion

Advantages

- Deionised H₂O for reconstitution
- Smaller Boxes
- Lower Price

Disadvantages

- Results influenced by H₂O quality



Conclusion

- Bicarbonate stability is better than the General Serum Chemistry material at the level tested
- The results support further investigation of the new formulation



2011 General Chemistry Diluent Pilot Study

- Aalto has manufactured Pilot Vials in conjunction with the 2011 General Chemistry Material
- 4 Levels
- Plan to repeat the study in May 2011



Acknowledgements



Good Idea?





Troponin I Replacement Vial

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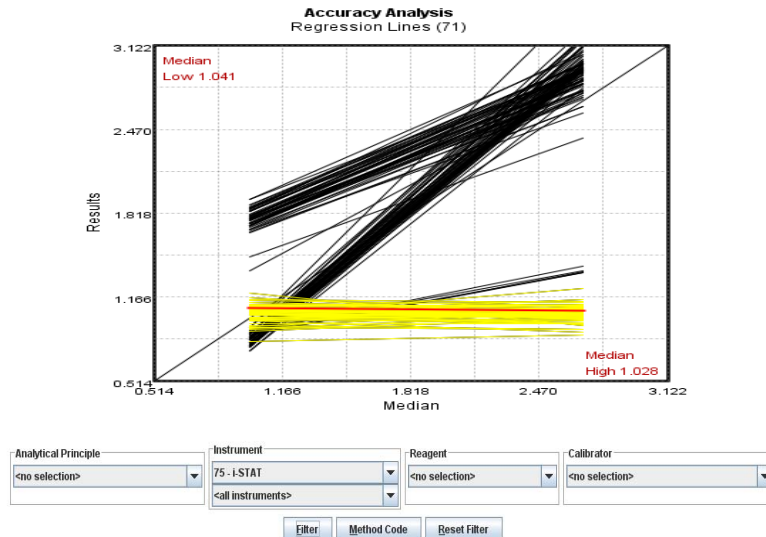
Troponin I Replacement Vial

i-STAT AND VITROS ECi USERS – TROPONIN I NON-LINEARITY

- The QAP has noted that the Abbott i-STAT instrument and the OCD Vitros ECi instrument do not achieve a linear response with our 2010 General Serum Chemistry QAP material. Please ensure that you review your results against your specific instrument peer group on your QAP reports.
- The QAP is continuing to investigate this situation which was not present in the 2009 General Serum Chemistry QAP material.



Troponin I Group B – GC83



Instrumentation Affected

- Abbott i-STAT series 300
- Biomerieux Mini-Vidas
- Biosite Triage Meter
- Radiometer AQT90 Flex
- Vitros Eci/ECiQ, Vitros 5, 1FS/5600



Solution

- Arranged the manufacture of separate vials of Troponin I material
- The vials were supplied free of charge by the manufacturer to current participants
- Distributed to laboratories using the affected instrumentation that were enrolled as at 30 June 2010
- For use in conjunction with Cycle 85 of the General Serum Chemistry Program



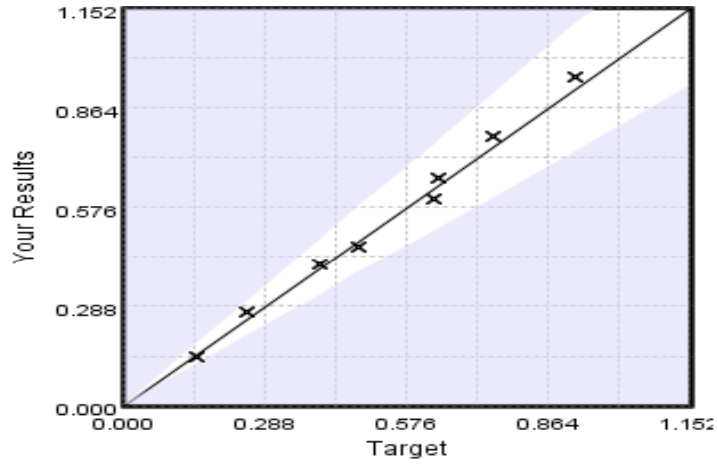
Reports

GROUP	MEASUREMENT SYSTEMS	MATERIAL
Troponin I New Material	Abbott i-STAT series 300	Separate vial
	Biomerieux Mini-Vidas	
	Biosite Triage Meter	
	Radiometer AQT90 Flex	
	Vitros Eci /ECiQ	
	Vitros 5, 1FS/5600	
Troponin I Group B	Abbott Architect i1000SR	Main GC vial
	Abbott Architect i2000-i8000	
	Abbott Architect c16000	
	Siemens ADVIA Centaur/XP	
	Siemens ADVIA Centaur CP	
Troponin I Group A	All other instruments	Main GC vial



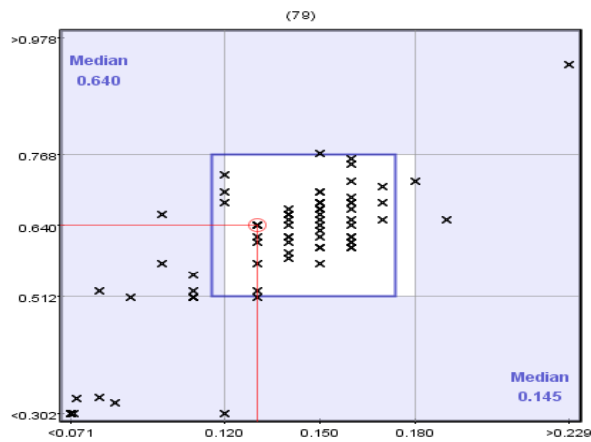
Results

Troponin I New Material



Results

Troponin I New Material





Limitations

- Unable to provide separate Troponin I material to those laboratory's changing to the affected instrumentation after 30 June 2010
- Asked these laboratories not to submit results for Troponin I for Cycle 85 of the General Serum Chemistry Program
- Provided a reference letter to explain the situation



2011 Troponin I

- The investigation and solution provided an improvement opportunity
- The provision of a separate vial for Troponin analysis
- In 2011 we are offering a PoCT Troponin Program suitable for PoCT devices
- Particularly aimed at laboratories who used to enrol in either GC or NP for Troponin only



QAP Process

- The RCPA Chemical Pathology QAP is continually
 - **monitoring**
 - **developing**
 - **improving**
- The QAP aims to keep its program participants **informed** and **involved** in this process and the subsequent outcomes and/or ongoing investigations which are being undertaken.

