

Centre for
Development
Innovation



Capacity building to improve the Malaysian inspection and monitoring systems for aquaculture and fisheries products

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Training Report



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Project: Capacity building improve Malaysia's inspection and monitoring system for aquaculture and fishery products (BO-10-001-217)

This research project has been carried out within the Policy Supporting Research task for the Ministry of Economic Affairs, Theme: Robust Systems, Cluster: International Cooperation.

The course was implemented in partnership by Institute of Food Safety (RIKILT), Wageningen UR.



Capacity building to improve the Malaysian inspection and monitoring systems for aquaculture and fisheries products

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The project aimed to help build a credible inspection and monitoring system that can guarantee safe quality products of Ministry of Health (MoH) and Department of Fisheries (DoF) by upgrading the analytical capacity of the laboratory staff directly involved in the analysis and detection of forbidden substances. Two training courses were implemented at the beginning of 2013 in the Bio Security Centre in Kuala Lumpur, Malaysia. The first training course on 'Quality Assurance and Validation of Chemical Methods' has been implemented in March and the second training course on Method Validation of qPCR Analysis was implemented in April 2013. Through this knowledge transfer and laboratory enhancement the project contributed the laboratory's process towards getting accreditation under ISO 17025. The courses were implemented in partnership by Institute of Food Safety (RIKILT), Wageningen UR and Centre for Development Innovation (CDI), Wageningen UR.

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1 Quality Assurance and Validation of Chemical Methods

25-29 March, 2013

Fisheries Biosecurity Centre, Kuala Lumpur, Malaysia

Bjorn Berendsen, Robin Wegh, Ingrid Gevers

Summary

The Department of Fisheries of Malaysia is recognised as a Competent Authority by the EU since 2010. It has issued tenders to purchase more advanced test equipment such as GC- TOF/MS, ICP-MS and additional LC-MS/MS to enhance the number of samples and parameters to be analysed in the laboratories. Consequently there is a need to improve the capability and competence of the technicians and laboratory staff manning and operating these equipment's. There is not only a need to upgrade the analytical capacity of the laboratory staff directly involved in the analysis and detection of forbidden substances, but also to improve their skills and knowledge to analyse additional parameters. Through knowledge transfer and laboratory enhancement this BOCI project will support the laboratory's process towards getting accreditation under ISO 17025.

The short term objective of the BOCI project is to increase the knowledge and skills of the Department of Fisheries (DoF) as EU-accredited competent authority (CA). The long term objective is to have a national body that provides good governance, effective control over the entire production chain from farm to table, with the ultimate goal to help build a credible inspection and monitoring system that can guarantee safe quality products.

The project follows a training of training approach that allows the Department of Fisheries in Malaysia to increase the capacity and competence of all relevant staff on methods of analyses over a wider spectrum of parameters. Subsequently this will result in improved Laboratory Services as an important component of the Food Safety and Quality Assurance System. Eventually the greater capacity and capability of the laboratories and their staff will result in accreditation for official analyses.

Originally the course was intended to be implemented in 2012 but due to construction of new laboratory facilities the course was postponed to 2013. Consequently a new needs assessment was done and the training programme shifted its focus towards method validation. The first training course on 'Quality Assurance and Validation of Chemical Methods' has been implemented from 25-29 March 2013. The course was implemented in partnership by Wageningen UR Institute of Food Safety (RIKILT) and Wageningen UR Centre for Development Innovation (CDI). RIKILT provided the expertise on method validation and the design of the technical part of the training programme. CDI was responsible for the overall project management and facilitation of a dialogue around ISO certification during implementation of the training course and bringing more interactive tools into the course to enhance learning.

A total of 10 participants working at different laboratory of the Biosecurity Centre under the Department of Fisheries in Malaysia participated in this course (see Annex I). The training was guided by the aim of the Fisheries Biosecurity Centre to obtain laboratory accreditation (ISO 17025). The course was highly interactive using a combination of theoretical interactive PP presentations, assignments and group work. Theory and practice were alternated throughout the course.

The daily course programme is given in Annex II. As mentioned before, the course topics were not in line with the course objectives described in the original proposal of the course but were changed based on the needs and expectations of the Department of Fisheries. .

To assess if the training activities were indeed relevant for the participants and contributed to building a credible inspection and monitoring system that can guarantee safe quality products monitoring, the training course included an evaluation focusing on content and methodology used. Following you can find a short description of the different daily sessions included in the training course.

Day 1, March 25

Introduction to the course

The first day started with a getting to know session. The participants were asked to introduce themselves individually by answering the following questions:

1. What is your name, what organisation do you work for and what is your position?
2. How much experience do you have with the operation of LC-MS/MS?
3. How much experience do you have with validation?
4. How much experience do you have with statistics?

Some participants of the course have experience working with LC-MS/MS. Almost none of them have experience with validation or statistics.

After the getting to know the participants were asked to share what they hoped to learn during the course. Each of them was asked to write their expectations down on coloured cards. The cards of all participants were presented and grouped. The majority of learning objectives involved validation in general, measurement uncertainty and quality assurance. The learning objectives can be found in Annex III. Finally house rules were discussed and agreed upon.

Legislation and Quality Assurance

First a short introduction to quality assurance was given by Bjorn Berendsen of RIKILT and in plenary it was discussed why accreditation is important to the Department of Fisheries in Malaysia. The participants were then divided into small groups and asked to list the top 5 of most important issues of quality assurance. After 15 minutes discussion the results of each group were presented (SEE PICS TO SUMMARISE) to each other followed by a PP presentation about ISO17025 which discussed the technical and the managerial requirements. Reference was made to the existing situation of the laboratories in Malaysia. It was emphasised that the requirements of accreditation should be clear to all staff and management. Everybody should be aware on what it entails. From a management perspective it is for example important that the staff are properly trained and supervised, all documents are controlled and a clear management system is present. The technical aspects are more laboratory based and examples were given such as identification/labelling of equipment and chemicals, and regularly check performance of all equipment.

All laboratories, Sarawak, Kuantan and KLIA (already accredited by ISO) have their own quality manuals in place. It is emphasised that all staff need to have seen this manual as part of the ISO accreditation procedure and need to proof to SAMM (Malaysian accreditation authority) that all requirements are followed.

Note:

Not all laboratories are at the same level of accreditation. The Biosecurity Centre in Kuala Lumpur aims to have the laboratories accredited by the end of 2013. Kuantan is aiming first for accreditation for microbiological analysis by the end of 2013 and heavy metals by 2014. Sarawak aims for ISO certification for viruses by the end of 2013. Penang is a research lab and does not go for accreditation.

Screening and confirmation

After lunch a PP presentation explaining the differences between a screening method and a confirmatory method was given by Robin Wegh of RIKILT. In this, the difference between a screening and a confirmation method, as well as between a qualitative and a quantitative method were explained. From the response it was clear that all participants were aware of the different types of methods applied in the laboratory. Clearly the expertise and focus of most participants was on quantitative confirmatory methods.

Validation and accreditation

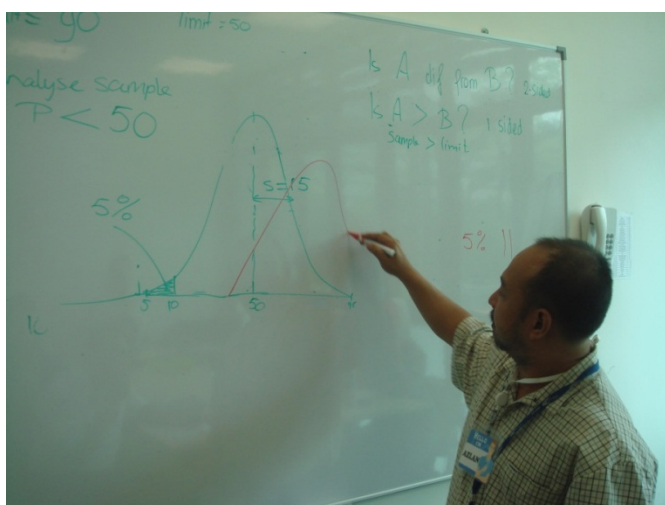
The most relevant legislation on validation was explained by Robin Wegh of RIKILT including 2002/657/EC (veterinary drugs analysis) and SANCO 12495/2011 (pesticide analysis). Furthermore the difference between the initial and on-going validation was explained. Because 2002/657/EC describes the most extensive initial validation, it was agreed upon to focus on this document for the practical exercises.

Next, all relevant performance characteristics were defined by a highly interactive PP presentation given by Robin Wegh of RIKILT. The performance characteristics were clearly explained and discussed. From the interaction with the participants it became clear that they all had a good general idea on the definition of the performance characteristics. Especially repeatability versus within-laboratory reproducibility needed some further explanation.

The participants were divided in small groups to work on an exercise. The groups were to identify which performance characteristics are relevant for a validation of (a) a quantitative screening, (b) a quantitative screening, (c) a qualitative confirmatory method and (d) a quantitative confirmatory method. After open discussions within the groups the results of each group were presented on a poster. For each performance characteristics one participant was asked to explain the choices made and after some discussion the final result was compared with the guidelines in 2002/657/EC. With this exercise a good understanding of all performance characteristics was obtained. Furthermore, a clear overview of what performance characteristics to validate depending on the type of method was obtained.

Measurement uncertainty

Just before the end of the first day, an introduction on method uncertainty and decision making was given by Bjorn Berendsen of RIKILT. Clearly, the participants struggled with the concept of standard deviation, confidence intervals and were therefore not ready to familiarize themselves with the concept of the decision limit ($CC\alpha$) and detection capability ($CC\beta$).



Day 2, March 26

Reflection

Ingrid Gevers of Wageningen UR- Centre for Development Innovation facilitated this session. Some additional explanation was requested on the calculation and interpretation of confirmatory parameters. Because this aspect would not hamper the continuation of the training process, this question was postponed and discussed in detail on Friday. To obtain insight in the participants' understanding of the final topics of day 1, the reflection started with an exercise in which a confidence interval had to be calculated from given data. Clearly the trainers needed more elaboration on this topic.

Measurement uncertainty

Even though the training was already behind of schedule, the RIKILT trainers found it of prime importance that the participants understood the concept of the confidence interval and the related performance characteristics $CC\alpha$ and $CC\beta$. Therefore, Bjorn Berendsen of RIKILT spent extra time on the explanation of these concepts in a highly interactive way until clearly most participants understood the importance of these parameters and the effect on the decision making process.

Recovery and Matrix effects

In general, recovery is a poorly understood performance characteristic and is not clearly described in 2002/657/EC. Furthermore, the matrix effect is a relatively new concept that is not included in 2002/657/EC. To achieve a better understanding of recovery and matrix effects, after lunch, a PP presentation was given by Robin Wegh of RIKILT on this topic. The parameters were explained in a highly interactive way in which the participants had an active role. This resulted in a clear understanding of the definition of apparent and true recovery, and the matrix effects. Next, the participants were divided in small groups and worked on the calculations for preparation of quality control samples needed for correct determination of the true recovery and the matrix effect. This exercise added much to the participants' understanding of preparing quality control samples.

Basic statistics

To be able to understand and calculate performance characteristics of a method of analysis some basic statistical understanding and skills are mandatory. This afternoon a PP presentation on basic statistic techniques was given by Bjorn Berendsen of RIKILT. The comparison of two populations using a Students' t-test was quickly understood and here it was apparent that the concept of standard deviation and



confidence intervals as discussed during day 1 and 2 was very much clear to the participants. The participants were divided in small groups and worked on an exercise applying the statistical test learned in a real situation. Here it became clear that the experience working with all main possibilities in Excel software hampered quick calculations and because no references within a work sheet are used, chances on mistakes are severe. Therefore some simple functions in Excel were explained by the RIKILT trainers.

Day 3, March 27

Reflection

Ingrid Gevers of Wageningen UR- CDI Innovation asked the participants to write down on coloured cards the most important things learned during the first two sessions given on day 2. Also the topics that needed more attention were listed. For the first measurement uncertainty session, the concept of CC α and CC β was well understood and was indicated by most participants as the most important thing learned. From the drawings made on the evaluation forms, it was clear that most participants learn best from highly visual teaching methods. For the second session, the way to calculate the recovery and the matrix effects were the most important. Also here, many drawings were made to visualise the subject. Both RIKILT trainers were glad to see that the difficult topics discussed had now clearly been understood by the participants and this demonstrated that the additional time taken to explain especially the concept of measurement uncertainty was worth the time. The topics that were not yet clear were listed on the whiteboard for the trainers to come back to at a later stage in the training.

Basic statistics

After the reflection, the session on basic statistics was continued. In a PP presentation it was demonstrated how to compare more than two populations using a simple statistic test and how to calculate within and between group standard deviations from this. Again the participants were divided in small groups to work on an exercise and next it was demonstrated by the RIKILT trainers how this test is applicable in a quantitative validation. From the questions asked and the discussion, it was clear that the participants understood how to carry out these calculations and with some practice, they should all be able to perform these calculations after the training.

Validation screening method

Because a lot of extra time was spent to get across the basic principles of statistics at day 1 and 2, it was not possible to complete the whole program as planned. Because the emphasis of most participants is on quantitative methods, it was decided that the procedures on the validation of a screening method would not be discussed in detail. Another training on screening analysis and validation could be useful, so screening methods are more widely applied throughout the laboratories. This would increase efficiency of the workflow and could increase the sample throughput and lower the total costs. In such a course, the validation of a screening method would be in place.

Validation quantitative method

The afternoon started with a PP presentation on the performance criteria as mentioned in 2002/657/EC given by Robin Wegh of RIKILT. Furthermore, it was demonstrated what the four phases in a validation are, being (1) preparation of the validation plan, (2) analyses in the lab, (3) data evaluation and calculations and (4)



reflection of the results with the criteria mentioned in the validation plan. The procedure of making a validation plan and establishing method performance criteria was clearly new to the participants.

After all procedures for carrying out a complete validation were discussed, the groups were divided in small groups based on their personal interests (working with banned or registered compounds). Each group were to define the performance characteristics that should be determined and to establish the criteria. Each group presented their results on a poster, which could be considered a summary of the validation plan.

Day 4, March 28

Reflection

During the reflection the participants asked each other questions related to assess the level of learning of the day before. First questions about the most important things learned and the most difficult parts were discussed. Next questions regarding the content of the training to see if all important aspects of the training were well understood. Based on the questions asked and the answers given it was clear that the procedures for validation were clear to most participants.

Validation quantitative method continued

As a follow-up of day 3, the participants were given complete validation datasets obtained from RIKILT. In an exercise, again in small groups, the participants had to calculate all relevant performance characteristics from the data. To be able to do this, all the lessons learned at day 1 through day 3 had to be applied. Even though it took a lot of time, mainly because of the lack of experience working with Excel, all groups were able to calculate the performance characteristics in the correct way. Each group wrote the calculated results on a poster which was stored for later reference.

Stability, Ruggedness, and Selectivity

Using a PP presentation the relevant performance characteristics, not yet discussed, were presented by Robin Wegh and Bjorn Berendsen of RIKILT. A discussion was started on the differences between ruggedness and within-laboratory reproducibility took place demonstrating a critical view and perseverance for understanding also the details of validation.

Validation report

Finally, in an interactive way the last step of the validation process was demonstrated. The posters made by the participants containing the performance criteria and the posters showing the calculated results were compared. For each performance parameter it was decided whether or not it was acceptable and if not, what to do. During this session everything fell into place and participants expressed their understanding of the process and the importance of all the individual steps. Next, a complete validation report, as prepared at RIKILT, was shown and discussed. The report was left with the participants as a reference.



Day 5, March 29

Monitoring method performance

In this session the different roles in the laboratory and the quality control samples needed according to ISO 17025 were discussed using a PP presentation given by Robin Wegh of RIKILT. Furthermore, the use of these quality control samples for on-going validation was clearly demonstrated. The participants showed good understanding of the different quality control samples and understood their use for assessment of the method used.

Questions

Before the break the questions that appeared and were parked on the white board during the whole week were discussed. These included, among others, the calculation of the ion ratio and which was explained by Robin Wegh of RIKILT. Further emphasis was given to the fact that this was the last opportunity to ask questions by writing them on the whiteboard. After the break some additional questions appeared and were discussed.

Evaluation of the training

The training was evaluated by means of a written questionnaire. The participants were asked to score the:

- Overall appreciation of the course
- Facilitation
- Course methods and resources
- Balance theoretical and practical content
- Balance lectures and interactive group work

and to give the reasoning behind the score.

They were asked to what level their knowledge, skills and self-confidence had improved and where asked to answer the following open questions:

1. Please describe the overall relevance of the course to your work and your learning needs
2. Which topics of the course did you find MOST relevant and why?
3. Which topics of the course did you find LEAST relevant and why?
4. What are your 3 key lessons from this course and why are these so valuable to you and your work?
5. Please share which actions you will take after having participated in the course in relation to your work?
6. What will be the first step(s) you will take within the coming 3 months?

And finally they were asked to provide feedback to the facilitators; what was good and what could be improved.

The evaluation conducted at the end of the course showed that all participants felt that the quality of the course was excellent, was very relevant to their work and that the majority of the objectives of the course were met. As a result they felt to be much more confident to start the method validation process in their respective laboratories. Most participants were satisfied with the facilitation of the training and appreciated the learning process and how individual and group needs were balanced. They appreciated the interactive approach that was followed and the combination of theory with practical sessions. The RIKILT facilitators were found to be very knowledgeable in method validation and taking sufficient time to explain the subject matter. The results of the evaluation can be found in Annex IV.

After the evaluation the course was closed and certificates were handed out.

Findings and Recommendations

First of all, the participants were very eager to learn from the experts and they gained a lot of knowledge on method validation. However it was noted that the background and the level of the participants is very diverse.

Some other lessons learned during the training course were the following:

- During the training it became clear that only a limited number of the participants was actually planning to carry out a validation in 2013. Because this is a complicated topic, it is advisable to practise a lot and to work with the lessons learned immediately after the training.
- There is not too little communication among the different laboratories. It is advised to share experiences on methods of analysis of the same type and to challenge other laboratories in case of ambiguities because this would strengthen the dissemination of knowledge.
- It is advised to collaborate in validation and to establish a quality control system that covers all laboratories involved in the same type of analysis (e.g. by organizing inter-company proficiency tests). RIKILT would be able to assist in the organization of such tests by preparing samples or by giving a training on this topic.

It is advised to invest in method development and trouble shooting. Understanding of these aspects will enable the laboratories to become more efficient and be able to cope with minor problems that regularly occur during residue analysis.

ANNEX I – LIST OF PARTICIPANTS

*Quality Assurance and Validation of Chemical Methods
Fisheries Biosecurity Centre, Kuala Lumpur, Malaysia
March 25-29, 2013*

No.	Name	Present Position	Centre	Nature of Work
1.	Azlan Bin Md. Nor	Fisheries Officer	Fisheries Biosecurity Centre Kuantan, Pahang	Heavy metal analysis in fish using LC-ICP-MS
2.	Zarina Binti Zainuddin	Fisheries Officer	Fisheries Biosecurity Centre Kuala Lumpur	Veterinary Drug residue analysis in fish using LCMSMS.
3.	Haliza Binti Sulaiman	Fisheries Officer	Fisheries Biosecurity Centre Bintawa, Sarawak	Pesticide residue analysis in fish using GCGC-ToF-MS and histamine analysis in fish using HPLC.
4.	Chai Pui Shan	Fisheries Officer	Fisheries Biosecurity Centre Bintawa, Sarawak	Veterinary Drug residue analysis in fish using ELISA and LCMSMS.
5.	Roziah Binti Mat Zin	Fisheries Officer	Fisheries Biosecurity Centre Kuantan, Pahang	Pesticide residue analysis in fish using GCGC-ToF-MS and histamine analysis using HPLC.
6.	Zahari Bin Awang	Assistant Research Officer	Fisheries Biosecurity Centre KLIA, Sepang	Water quality analysis.
7.	Rohana Binti Shapiin	Assistant Research Officer	Fisheries Biosecurity Centre Kuala Lumpur	Pesticide residue analysis in fish using GPC-GCMS
8.	Bakri Bin Saad	Assistant Science Officer	Fisheries Biosecurity Centre Kuantan, Pahang	Histamine analysis in fish using HPLC, Biotoxine analysis using HPLC, and Heavy Metal analysis in fish using LC-ICP-MS.
9.	Noor Aishah Binti Wahab	Assistant Science Officer	Fisheries Biosecurity Centre Kuantan, Pahang	Veterinary Drug residue analysis in fish using ELISA and LCMSMS.
10.	Siti Nadirah Binti Abdullah	Assistant Science Officer	Fisheries Biosecurity Centre Bintawa, Sarawak	Analysis in marine biotoxin using HPLC.

ANNEX II – COURSE PROGRAMME

Training on Quality Assurance and Validation of Chemical Methods 25 – 29 March 2013

Day 1 – Monday

Time	Subject	Type
09:00 – 09:45	Introduction trainers and participants	-
09:45 – 10:45	Aim of the training, needs and expectations	Discussion
10:45 – 11:00	Tea break	-
11:00 – 11:30	Legislation on quality assurance (ISO 17025)	Lecture
11:30 – 12:30	Quality assurance issues	Exercise
12:30 – 14:00	Lunch	-
14:00 – 14:30	Screening versus confirmation	Lecture
14:30 – 15:30	Validation (incl. 2002/657/EC and SANCO 12495) and parameters	Lecture
15:30 – 15:45	Tea break	-
15:45 – 17:00	Selection of validation parameters	Exercises

Day 2 – Tuesday

Time	Subject	Type
09:00 – 09:30	Evaluation of day 1 and introduction to day 2	Discussion
09:30 – 10:00	Measurement uncertainty and decision making	Lecture
10:00 – 10:45	CC α and CCB	Lecture / exercises
10:45 – 11:00	Tea Break	-
11:00 – 12:00	CC α and CCB (continued)	Lecture / exercises
12:00 – 12:30	Recovery and matrix effects	Lecture / exercises
12:30 – 14:00	Lunch	-
14:00 – 15:00	Recovery and matrix effects continued	Lecture / exercises
15:00 – 15:30	Repeatability and reproducibility incl. basic statistics	Lecture / exercises
15:30 – 15:45	Tea Break	-
15:45 – 17:00	Repeatability and reproducibility incl. basic statistics continued	Lecture / exercises
20:15 – 22:00	Welcome Dinner	-

Day 3 – Wednesday

Time	Subject	Type
09:00 – 09:30	Evaluation of day 2 and introduction to day 3	Discussion
09:30 – 10:00	Validation of a screening method	Lecture
10:00 - 11.45	Designing a validation procedure for a screening method	Exercise
10:45 – 11:00	Tea Break	-
11:00 – 12:00	Designing a validation procedure for a screening method (continued)	Exercise
12:00 – 12:30	Data analysis for validation of a screening method	Lecture / exercises
12:30 – 14:00	Lunch	-
14:00 – 15:00	Data analysis for validation of a screening method continued	Lecture / exercises
15:00 – 15:30	Validation of a quantitative method	Lecture
15:30 – 15:45	Tea Break	-
15:45 - 17.00	Designing a validation setup for a quantitative method	Exercise

Day 4 – Thursday

Time	Subject	Type
09:00 – 09:30	Evaluation of day 3 and introduction to day 4	Discussion
09:30 – 10:30	Data analysis for validation of a quantitative method	Exercise
10:30 – 10:45	Tea Break	-
10:45 – 12:30	Data analysis for validation of a quantitative method (continued)	Exercise
12:30 – 14:00	Lunch	-
14:00 – 15:30	Stability, ruggedness and selectivity	Lecture / exercises
15:30 – 15:45	Tea Break	-
15:45 – 16:30	Validation report	Lecture / exercises
16:30 – 17:00	Analysis reports	Exercise

Day 5 – Friday

Time	Subject	Type
09:00 – 09:30	Evaluation of day 4 and introduction to day 5	Discussion
09:30 – 10:30	Monitoring method performance	Lecture / exercise
10:30 – 10:45	Tea Break	-
10:45 – 11:30	QA Session	Discussion
11:30 – 12:30	Evaluation, closing ceremony including certificates	-
12:30 – 13:30	Lunch	-

ANNEX III – LEARNING OBJECTIVES

Reporting

- Learn to do a method validation report (2)

Measurement Uncertainty

- Learn more for measurement of uncertainty
- Including MU
- Learn about measurement uncertainty
- $CC\alpha$ and $CC\beta$
- How to calculate the MU
- Method validation in measurement uncertainty, $CC\alpha$ and $CC\beta$

Quality Assurance

- How to do robustness in heavy metals analysis using ICP-MS
- Quality assurance (2)
- Quality assurance on tests conducted

Method Validation

- Hope to learn of method validation
- How to validate a method for analysis histamine using HPLC
- How to verify the method
- Validation procedure for method & result
- Know what is exactly method validation; HPLC & GC
- Learn to validate method using ICP-MS
- To understand the definition of method validation terminology
- Method validation on residue drug
- To know how to do method validation – steps
- The importance of method validation
- To validate the test method adopted
- To learn about method validation, how to validate the method of our analysis
- Understand and do method validation using HPLC and GC
- How to verify the method
- How to do method validation, if not involve the calibration curve etc. chromatography
- Proper way to conduct analysis to produce precise, reliable results

Data Analysis

- Significant statistics result
- Learn more about statistics
- To know to analyse the data using statistics for report – interpretation
- To know details about statistics

Materials

- Get the excel template about statistics
- Get the excel template to calculate all the data statistics

Trouble shooting

- Able to handle the trouble shooting

ANNEX IV – EVALUATION

OVERALL APPRECIATION OF THE COURSE

Overall quality of the course	Very poor	Poor	Adequate	Good	Excellent IIII II
Achievement of stated course objectives	Very poor	Poor	Adequate I	Good	Excellent IIII II
Have your expectations been met	Very poor	Poor	Adequate I	Good I	Excellent IIII I
Logical flow of the course programme	Very poor	Poor	Adequate	Good II	Excellent IIII I
Flexibility in the programme to meet your specific needs	Very poor	Poor	Adequate	Good III	Excellent IIII

Please explain the reasons behind your appreciation:

- All excellent because the training met the objective and met my expectations.
- The explanation from the trainers is clear and can be understand most after practical works.
- The course was fulfilled my needs in improving my knowledge in method validation
- Honestly the explanation from both Bjorn and Robin is very helpful to know more detail about method validation; many information and new knowledge I "get it".

FACILITATION

Clarity of presentations and directions	Very poor	Poor	Adequate	Good III	Excellent IIII
Overall guidance of group learning process	Very poor	Poor	Adequate	Good III	Excellent IIII
Interaction of facilitators and participants	Very poor	Poor	Adequate I	Good	Excellent IIII II
Facilitators' ability to balance group needs and specific individual needs	Very poor	Poor	Adequate I	Good I	Excellent IIII I

Comments

- Good and interaction of facilitator
- Trainers can give explanation to the individual question.
- The course was conducted in good environment.
- Facilitation with environment was very nice; comfortable to focus during lecture.

COURSE METHOD AND RESOURCES

Effectiveness of the training methods used	Very poor	Poor	Adequate	Good I	Excellent IIII II
Diversity of the methods used	Very poor	Poor	Adequate	Good II	Excellent IIII I
Adequacy of supporting written and web-based materials	Very poor	Poor	Adequate I	Good I	Excellent IIII I

Comments:

- The method used is easy to understand & can be referred after this course.
- The course method & resources were sufficient and very useful for reference & guidance.
- Course method is very suitable and easy for me to understand. Also resources.

BALANCE PRACTICAL AND THEORETICAL CONTENT

Balance between practical and theoretical content	Far too theoretical	Too theoretical	Just right IIII II	Too practical I	Far too practical
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BALANCE LECTURES AND INTERACTIVE GROUP WORK

Balance between lectures and interactive group work	Far too many lectures	Too many lectures	Just right IIII II	Too much group work I	Far too much group work
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AS A RESULT OF THE COURSE MY KNOWLEDGE, SKILLS AND SELF CONFIDENCE HAVE IMPROVED

Knowledge	Not at all	A little	Quite a lot II	A lot IIII I
Skills	Not at all	A little	Quite a lot IIII	A lot III
Confidence	Not at all	A little	Quite a lot III	A lot III

PLEASE ANSWER THE FOLLOWING OPEN QUESTIONS

1. Please describe the overall relevance of the course to your work and your learning needs:

- The course is relevant to my work because we need to do the validation for our analysis method in the process of getting the ISO 17025.
- The course is really relevant to my work because I really need to validate my analysis method, so that can go further to get the lab accreditation.
- For overall of the course are relevance to my work and I learned a lot of information regarding the method validation.
- It is important to me to understand & do the method validation for my lab. So the course is relevance to my work.
- The course relatively relevant as it enhanced the knowledge and technical knowhow in concluding the method validation.
- The course was really relevant to my work so that I can improve my knowledge and skills.
- Relevance to my work and the objective of the course.
- Overall relevance with my analysis histamine in lab using HPLC – method validation.

2. Which topics of the course did you find MOST relevant and why?

- The parameters & the data evaluation
- CC α & CC β is most relevant because it will be the guide for me to classify whether samples are comply or not
- All topics of the course most relevant because it cover for validation method.
- 1) The step to do method validation because I understand how to do validation. A) Plan – what parameters & criteria must have; B) Compare the performance to the man. 2) Validation report – know how to do validation report for my lab.
- Identifying the relevant parameters and criteria for method validation especially the M.U.
- The steps for method validation because I just do only for specific requirements.
- Quality assurance, MU, and the validation of parameter, which is the most important things to do the validation method.
- CC α and CC β ; Statistic to find the accuracy, repeatability within lab reproducibility; validation parameter.

3. Which topics of the course did you find LEAST relevant and why?

- All related to the banned substances because my work is more to the registered substances. But it is a good knowledge for me to learn something different from my work.
- All are relevant.
- All topic relevant and covered for method validation.
- Ruggedness and selectivity as these parameters are not applicable for simple analytical method using UV/ VIS Spectrophotometer
- No
- All of topics are most relevant because it is related to my work.
- MMS, MMRS least relevant because during my analysis histamine I never use MMS/MMRS

4. What are your 3 key lessons from this course and why are these so valuable to you and your work?

- 1) The ANOVA & all the statistics work; 2) Method validation plan; 3) Report
- 1) validation plan; 2) Statistic; 3) Validation report. With this 3 key lessons I could complete my method validation.

- I learned how to set up a validation plan for quantitative analysis. After this training I got a more confident to do method validation. I can learned a statistic and how to use ANOVA.
- 1) MU – learn how to find the MU; 2) Steps of method validation – know what the step must to do first & so on; 3) Validation report – clearly understand how to do the report because it is very important to have validation report.
- 1) Planning the work to be done as will help for the smooth flow of work; 2) Teamwork – participation between office colleagues and colleagues from other laboratories will aid in problem solving; 3) Sharing of information and working experience will help in solving problem when those problems arise.
- 1) More clearer what should be done for the method validation; 2) more confident to produce a result for the analysis; 3) practice makes perfect.
- Quality assurance, statistics and the plan of validation method.
- 1) validation parameter important for stop method validation; 2) Difference between qualitative and quantitative each validation parameter. Confirmation and screening.3) to know the collection of data.

5. Please share which actions you will take after having participated in the course in relation to your work

- Start to do validation plan just to get myself used to it. So it is easier for me when we start our method validation next year (probably) ☺
- I will immediately start with the validation process. I also will train my other colleagues who is not attending this course on how to validate their method.
- I will discuss with my colleague and plan to set up parameter and criteria for validation plan.
- I will start to do method validation for my lab reflect with the what I learn from this course.
- Will deliver the knowledge gained from the course to the rest of lab members.; Form a committee and start planning the work.
- A very good trainer, good explanation and good knowledge in the subject matter.
- I will start to do the method validation for my analysis
- Tell to my colleagues, then make a plan to do the validation method.
- I will do practice to make method validation for analysis histamine after back from this course.

6. What will be the first step(s) you will take within the coming 3 months?

- Do my QM
- First, I will make a validation plan. Then I will complete my method validation. After that, I hope that I will get the ISO 17025 accreditation.
- I will set up a validation plan and start to work for method validation.
- Firstly, I will make a plan for validation for my analysis & compare the data performance from lab analysis with the plan to check the method is suitable or not.
- (Will deliver the knowledge gained from the course to the rest of lab members.; Form a committee and start planning the work). It will be done as soon as possible within 3 months period.
- I will start to plan for my method validation
- Make plan to do the validation method, then do the analysis to get the data and then proceed to the validation method process.
- Discuss with colleague lab about to prepare method validation, set the criteria about validation parameter.

FEEDBACK FOR FACILITATORS/TRANERS

What positive (good things) and constructive (things to improve) feedback do you have for Bjorn

- Bjorn is good in explain the examples of relevant topics but have to do some improve in the other analysis like heavy metals
- Bjorn explains really well for his presentation only sometimes he speaks a little bit fast in the lecture
- Bjorn is a very good teacher. He always teach me even the question is so simple. Thank you sir for teaching me ☺ and now I like numbers/statistics
- Good: he tries so hard to explain and elaborate more the theoretical content in the slide.
Constructive: ok
- He's very good in method validation and ICMSMS, but it is good if the he can explain the method validation for other analysis using other instrument.; He can explained all the topics in detailed meaning the easier way to understand.
- Bjorn is very expert on this topic (method validation). He can explain everything regarding method validation. But he is quite serious in the class room, but he is very nice outside the classroom.
- We are lucky because Bjorn have good experience in method validation.
- Can give good explanation – easy to understand; Sometimes quite confused with some explanation.
- Very good trainer, good explanation and good knowledge in the subject matter
- He is good in conveying the lecture, so that I did understand.
- He is very good trainer and have a lot of knowledge in validation method. His presentation is very easy to understand. No more things to improve.
- Positive: explanation is very clearly easy to understand; easy to communicate and ask question;
Constructive: No.

What positive (good things) and constructive (things to improve) feedback do you have for Robin

- Robin also has the ability like Bjorn
- Robin explains very well also for his presentation
- Robin is a very good teacher. He explained all the things that I had not understand, step by step until I understand how to calculate it. Thank you ☺
- Good: he is a good looking man ☺. Constructive” need to elaborate more and slowly pronounce his words
- Need to improve on the presentation because he looks a bit shy; He is good in explaining the topics.
- Robin is very good in method validation; He is always smile.
- Robin also good trainer.
- Good in give explanation; Sometimes take times to answer question from participant (ask to Bjorn).
- Quite well versed in the subject matter.
- He is very nice to share his knowledge in this course. He just need to be more confident during the lecture, so that we don't get confused.
- He is very good trainer and have a lot of knowledge in validation method. The improve things is more confident in his presentation.
- Positive: same with Bjorn; Explanation about this course is clear. Easy to communicate and ask question. Constructive: No.

2 Training Course on Method Validation of qPCR Analysis

9-12 April, 2013

Kuala Lumpur, Malaysia

Jeroen van Dijk, Stephanie Zaaijer, Ingrid Gevers

Summary

The Department of Fisheries of Malaysia is recognised as a Competent Authority by the EU since 2010. Through knowledge transfer and laboratory enhancement this BOCI project will support the laboratory's process towards getting accreditation under ISO 17025. The short term objective of the BOCI project is to increase the knowledge and skills of Ministry of Health (MoH) and Department of Fisheries (DoF) as EU-accredited competent authority (CA). The long term objective is to have a national body that provides good governance, effective control over the entire production chain from farm to table, with the ultimate goal to help build a credible inspection and monitoring system that can guarantee safe quality products.

The project follows a training of training approach that allows the Department of Fisheries in Malaysia to increase the capacity and competence of all relevant staff on methods of analyses over a wider spectrum of parameters. Subsequently this will result in improved Laboratory Services as an important component of the Food Safety and Quality Assurance System. Eventually the greater capacity and capability of the laboratories and their staff will result in accreditation for official analyses.

Originally the course was intended to be implemented in 2012 but due to construction of new laboratory facilities the course was postponed to 2013. Consequently a new needs assessment was done and the course focus was adjusted accordingly. This training course on Method Validation of qPCR Analysis was a specific request from the Department of Fisheries following their desire to work towards ISO 17025 accreditation. This course was new in its kind since in the past the Dutch support has only been given to upgrading chemical analyses.

The course was implemented from 8-12 April in Kuala Lumpur, Malaysia. The course was implemented in partnership by Wageningen UR - Institute of Food Safety (RIKILT) and Wageningen UR Centre for Development Innovation (CDI). RIKILT provided the expertise on laboratory tests and - practices, and CDI was responsible for the overall design of the training curriculum, overall project management and bringing interactive tools into the course to enhance learning.

A total of 10 participants working at different laboratories of the Biosecurity Centre under the Department of Fisheries in Malaysia participated in this course (see Annex V). The daily course programme is given in Annex VI. The content and modules of the course were decided in close dialogue with the management of the Fisheries Biosecurity Centre. The course facilitators followed a flexible program that allows adaptation to the specific needs of individuals and the group. Each day the group reflected on the lessons learned the day before. The course included an 'end-of-course' evaluation in which the participants gave their feedback about the content of the course, the modes of instruction and the quality of the resource persons and facilitators. Additionally at the end of the course the trainers reflected on what they learned during the course and gave feedback for improvement.

Following you can find a short description of the different daily sessions included in the training course.

Day 1, April 8

Introduction to the course

The first day started with a getting to know session. The participants were asked to introduce themselves one by one and share their names, position and place they work at. After this, the participants were asked what they hope to learn during this week. The learning objectives can be found in Annex III. After agreeing on house rules the experts from RIKILT introduced themselves and provided an overview of the programme of the training.

Introduction to method validation

This session consisted of two PowerPoint presentations about the general aspects of a quality system, which is a prerequisite for ISO 17025 accreditation, and the way RIKILT has implemented this. The second focussed on the actual ISO 17025 demands. This theoretical session was directly followed by an interactive session, working in groups, checking the how much of this information was immediately reproducible by the participants, either from the presentations or from previous knowledge.



Day 2, November 15

Reflection

Ingrid Gevers of the Centre for Development Innovation, Wageningen UR facilitated all reflection sessions. The participants reflected back on what they learned the day before. They were first asked to write down the difference between a conventional and a real time PCR. It was clear from the answers that this was well understood. After that they were asked to define: trueness, repeatability, reproducibility, specificity, limit of detection and limit of quantification. Also the importance for being able to translate a formula from a guideline to practical situations was reemphasised. It appeared that not all parameters were clear yet, especially the limit of detection (LOD) was new to the participants. Consequently during day 2 more attention will be paid to this.

Introduction to qPCR

This session consisted of a PowerPoint presentation regarding general principles of PCR and qPCR. Some short intermediate exercises were done.

Validation of qPCR

This session consisted of a PowerPoint presentation on general guidelines for validation of qPCR as well as the way RIKILT has implemented this. Also the JRC and other websites were shown and explained, for finding relevant guidelines for several aspects regarding ISO norms, validation and accreditation.

Application of JRC guidelines

Two examples in the latest JRC/ENGL guideline for verification of qPCR GMO detection methods were performed interactively, participants worked hand-on in excel in pairs. The goal was to get acquainted with how to implement statistical formulas in guidelines into practical excel files.



Day 3, November 16

Reflection

The participants reflected back on what they learned the day before. They were asked individually; what do you need to do before you can validate your method? In a plenary they were asked to share this. The trainers stressed that you first need to think about what you want to prove (why?). Then think about what your test does (how?). Will it answer your question? If you do not know what the test is doing you do not need to do a validation since you will not know what to validate How many controls will be needed to get your answer? What is the limit of detection in relation to this? And can you prove it and what to include in your validation/verification report? Some useful extra files, found on the internet were added by one of the participants regarding the topic of the day before.

Translation of validation principles to own work

This part was highly interactive. Participants worked in groups on based on specific testing methods. First, all participants were asked to specifically describes the goal, test material and technique they were using as a basis for the groups. Several rounds of presentations by the groups to all participants and follow-up assignments were performed to come to a fine-tuning of what validation and accreditation means in their particular situation.

Day 4, November 17

Reflection

The participants reflected back and were asked the following questions:

- What is the limit of detection (LOD)?
- What types of LOD do you have?
- What steps will you take once back in your laboratory.

They also discussed in pairs what they learned and what remains unclear and needs more attention.

Validation strategies

The morning session and the first part of the afternoon were a continuation of the day before, leading to the practical question of the very next thing the participants were planning to do regarding method validation and accreditation after this course.

Laboratory safety

By special request, the second part of the afternoon dealt with laboratory safety, with emphasis on biological safety. A short introduction was given and an instruction video was shown that was commissioned by the former Ministry of VROM "Precies zoals het hoort" ("Exactly right"). Participants were asked to write down notes after which the notes were elaborately discussed.

Day 5, November 18

Reflection/Evaluation participants

The participants look at back at their expectations written down at the start of the training and agreed that the majority of the leaning objectives were met. Then they filled in filled a questionnaire and were asked to score (and giver the reasons why they scored it this way) the:

- Overall appreciation of the course
- Facilitation
- Course methods and resources
- Balance theoretical and practical content
- Balance lectures and interactive group work

They were asked to what level their knowledge, skills and self-confidence had improved and where asked to answer the following open questions:

- Please describe the overall relevance of the course to your work and your learning needs
- Which topics of the course did you find MOST relevant and why?
- Which topics of the course did you find LEAST relevant and why?
- What are your 3 key lessons from this course and why are these so valuable to you and your work?
- Please share which actions you will take after having participated in the course in relation to your work
- What will be the first step(s) you will take within the coming 3 months?



And finally they were asked to provide feedback to the facilitators; what was good and what could be improved.

The overall quality of the course was evaluated by the participants to be good to excellent and it was felt that the course objectives met the expectations. The continuous interaction between the facilitators and participants and the overall guidance of the learning process were much appreciated. The hands on training approach followed stimulated learning although some participants were missing supportive documents and reference documents. Some participants also felt that the course was too technical but most scored the balance of theory and practice to be adequate. The majority of the participants mentioned that the course was very relevant to their day to day work and that they became more confident to do method validation. The RIKILT facilitators were appreciated for their expert knowledge on the topics. The CDI facilitator for making the course interactive and creating a good learning environment.

The detailed evaluation results can be found in Annex VII.

After the evaluation the course was closed and certificated were handed out.

Recommendations

Throughout the course the trainers have noted down points that need additional attention.

Recommendations for improvement:

1. The labs are well equipped. It is now of utmost important to keep developing the knowledge and (practical) skills of the laboratory staff that have to operate them. It is crucial that the laboratory staff keep practicing the newly learned methodology and knowledge.
2. It is essential to become more efficient in the exchange of knowledge and experience between the different laboratories in the country and to continue a learning process at organisational level. Suggestions on how this could be approached are:
 - a. The different labs in Malaysia (DOF) should support each other in capacity development. Some staff have more experience than others. Let them function as resource persons during internal training course to exchange knowledge.
 - b. Share the approach for method validation between laboratories in Malaysia. If one lab has already validated a certain method other labs can learn from this and benefit.
 - c. Link to an international research network to set up validations and ring trials
 - d. Develop excel skills and other basic spread sheet and statistical skills.
 - e. Set up a central quality control system with a quality officer that coordinates all validation and accreditation processes and organises internal audits

ANNEX I – LIST OF PARTICIPANTS

*Training on Method Validation of qPCR Analysis
April 8-12, 2013
Fisheries Biosecurity Centre, Kuala Lumpur, Malaysia.*

No.	Name	Present position	Centre	Nature of work
1.	Roslan Bin Abu Hasan	Fisheries Officer	Fisheries Biosecurity Centre Kuala Lumpur	Bacteriology analysis in fish and fish product
2.	Dr. Roslina Binti Ahmad Nawawi	Research Officer	Fisheries Biosecurity Centre Kuala Lumpur	Porcine ID analysis in fish and fish product using Real Time PCR
3.	Ainul Yasmin Binti Md. Yusoff	Fisheries Officer	Fisheries Biosecurity Centre KLIA, Sepang	Virus analysis in fish using Real Time PCR
4.	Ahmad Saifullah Bin Mohammad	Fisheries Officer	Fisheries Biosecurity Centre Kuantan, Pahang	Bacteriology analysis in fish and fish product.
5.	Rosliadi Bin Rahim	Fisheries Officer	Fisheries Biosecurity Centre Johor	Histopatology analysis in fish using tissue processor and microscop.
6.	Zawati Binti Awang	Assistant Research Officer	Fisheries Biosecurity Centre KLIA, Sepang	Bacteriology analysis in fish and fish product.
7.	Azmar Hana Elliany Binti Azhar	Assistant Research Officer	Fisheries Biosecurity Centre Johor	Virus analysis in shrimp using PCR.
8.	June Moh Hwei Yieng	Fisheries Officer	Fisheries Biosecurity Centre Bintawa, Sarawak	Virus analysis in shrimp using Thermocycler (PCR machine) , Water quality and parasitology using compound microscope and stereo microscope.
9.	Aranja @ Suna a/p Fong	Assistant Research Officer	Fisheries Biosecurity Centre Kedah	Virus analysis in fish using Real Time PCR and Bacteriology analysis in fish and fish product.
10.	Khaitrul Ediana Binti Mohd. Tahir	Assistant Research Officer	Fisheries Biosecurity Centre Penang	Virus analysis in fish using PCR.

ANNEX II – COURSE PROGRAMME

Day 1 – Monday

Time	Subject
08:30 – 09:00	Registration of participants
09:00 – 10:00	General introduction and program briefing by expert
10:00 – 10:15	Tea break
10:15 – 12:30	Getting to know each other: The Malay experience with biological analyses
12:30 – 14:00	Lunch
14:00 – 15:30	Lectures and discussions: Introduction to method validation, lab safety and quality management
15:30 – 15:45	Tea Break
15:45 – 17:00	Lectures and discussions: Introduction to method validation, lab safety and quality management

Day 2 – Tuesday

Time	Subject
09:00 – 09:30	Evaluation of day 1 and introduction to day 2
09:30 – 10:00	Introduction qPCR
10:00 – 10:15	Tea break
10:15 – 12:30	Validation of a qPCR method (RIKILT, ENGL)
12:30 – 14:00	Lunch
14:00 – 15:30	Exercise: Application of JRC guidance document for qPCR validation, including calculating examples
15:30 – 15:45	Tea Break
15:45 – 17:00	Exercise: Application of JRC guidance document for qPCR validation, including calculating examples

Day 3 – Wednesday

Time	Subject
09:00 – 09:30	Evaluation of day 2 and introduction to day 3
09:30 – 10:30	Discussion: Translation of validation principles to other biological test systems
10:30 – 10:45	Tea Break
10:45 – 11:30	Discussion: Translation of validation principles to other biological test systems
11:30 – 12:30	Working in groups
12:30 – 14:00	Lunch

14:00 – 15:30	Working in groups, continued
15:30 – 15:45	Tea Break
15:45 - 17.00	Working in groups, continued

Day 4 – Thursday

Time	Subject
09:00 – 09:30	Evaluation of day 3 and introduction to day 4
09:30 – 10:45	Presentations by groups
10:45 – 11:00	Tea Break
11:00 – 12:30	Discussion of initial validation strategies
12:30 – 14:00	Lunch
14:00 – 15:30	Lecture: Interlaboratory validation, ring trials, proficiency tests etc.
15:30 – 15:45	Tea Break
15:45 – 17:00	Discussion: Recapitulation, lessons learned

Day 5 – Friday

Time	Subject
09:00 – 09:30	Evaluation of day 4 and introduction to day 5
09:30 – 10:30	Evaluation of the course, questions, general discussion
10:30 – 10:45	Tea Break
10:45 – 11:30	QA Session
11:30 – 12:30	Closing ceremony including certificates
12:30 – 13:30	Lunch

ANNEX III – LEARNING OBJECTIVES

Lab safety general

- Lab safety for biological lab (ISO 17025)
- Want to know detail on simple lab safety – chemical using

Instruction qPCR

- To be able to learn how quantitative analysis is done and interpret in biological analysis

Data interpretation

- To be able to 'fight' my result / analysis
- To increase the quality and reliability of virology (PCR) and histopathology test.

Method validation verification

- What is method validation actually
- How, when to do method validation? Who supposed to do?
- How method validation and QA is done to be applied to our analysis and ISO documentation.
- What is method validation? (important criteria) Need to know??
- Differences between method validation and method verification.
- How to conduct the method validation in bacteriology analysis.
- How to do a simple method validation
- How is important method validation in analysis
- I want to know how to do method verification
- How to do method validation by using technic from other lab?
- To learn about how to do method validation in virology and histopathology methods.
- How to do method validation in bacteriology
- To confirm that whatever I'm doing now is the right way
- How to know limitation of detection for analysis kit?

Measurement Uncertainty (MU)

- How to calculate MU in biological method
- To know about method validation in biological analysis (how to calculate MU)
- To comply the ISO 17025: 2005 requirement for PCR and EUS analyses

ANNEX IV – EVALUATION

OVERALL APPRECIATION OF THE COURSE

Overall quality of the course	Very poor	Poor	Adequate	Good IIII III	Excellent III
Achievement of stated course objectives	Very poor	Poor	Adequate	Good IIII I	Excellent IIII I
Have your expectations been met	Very poor	Poor	Adequate I	Good IIII III	Excellent III
Logical flow of the course programme	Very poor	Poor	Adequate	Good IIII IIII I	Excellent I
Flexibility in the programme to meet your specific needs	Very poor	Poor	Adequate II	Good III	Excellent IIII I

Please explain the reasons behind your appreciation:

- This is a good training because before this I'm not clear about method validation and how/where to start.
- For overall, I think this is a very good course that I have attended and the objective and expectation of this course achieve.
- The objectives of the course is met as well as my expectation on what do I want to learn in coming to this course. It may not be the main objective of what the presenter is supposed to deliver, but I do really appreciate that they were able to adjust them based on what we are doing and our needs.
- Now I clear on method validation, LOD and safety that my objective for here.
- The objectives of the training are clear and at the end of the week all have been met. On the 1st day we were asked to write down our aim/goal for the training and gratefully we have that too.
- I think the course is too short to cover both method validation & quality assurance. We need another course (Ingrid please...) just for measurement uncertainty.
- I find it is an excellent quality of the course because I can be able to understand the objectives that in a short time. I only think it will be better if we can practice calculating the validations process after we understand the theory.
- The course is very good for understand what is LOD and what exactly method validation process but about Biosafety lab, not much information that I get.
- Lot of thing I learn in this course. Before this course I don't know how to doing validation method and finally I can apply this information to my lab next.
- The way you are conduct this training make me better understanding the subject matter. Time management also good.
- Overall appreciation of the course are amazingly good.
- Sometimes the reflection time is too long. E.g. We did ISO / IEC 17025 requirement the whole afternoon and the next morning we took quite some time in that again. For me it's quite redundant.

FACILITATION

Clarity of presentations and directions	Very poor	Poor	Adequate	Good IIII IIII	Excellent II
Overall guidance of group learning process	Very poor	Poor	Adequate	Good IIII	Excellent IIII III
Interaction of facilitators and participants	Very poor	Poor	Adequate	Good II	Excellent IIII IIII
Facilitators' ability to balance group needs and specific individual needs	Very poor	Poor	Adequate	Good IIII	Excellent IIII II

Comments:

- Overall, the presentations from the facilitators are excellent
- For me, what the facilitators give in talk is best, and the way and how she/he conduct the presentations OK.
- The overall facilitation is very good. They understand and concern about what we were doing and keep us on track by giving us exercise in groups.
- They try to know and help in specific individual needs.
- Been used to lot of training which did team or group work, but in this training, they do it differently. No fix group, so we tend to learn from others a lot. The facilitators are very friendly and very patient in our lack of knowledge.
- I think the facilitators have done a great job in this training. The fact that this training is considered a “boring” title, they have turned it into a fun learning training.
- We sometimes can't remember the notes in the presentations, but still can manage to understand during discussion.
- Good presentation and divide group with same basework is very effective. But the trainer is not enough experience in qualitative PCR and it make difficult to us to ask advice to our lab.
- Overall is good and easy for me to understand what our facilitation present and teach.
- Very good presentation and direction, guidance and I like the interactive part.
- The facilitation of the course are very helpful

COURSE METHOD AND RESOURCES

Effectiveness of the training methods used	Very poor	Poor	Adequate	Good IIII IIII	Excellent III
Diversity of the methods used	Very poor	Poor	Adequate I	Good IIII III	Excellent III
Adequacy of supporting written and web-based materials	Very poor	Poor	Adequate II	Good IIII II	Excellent III

Comments:

- Interesting
- The training method is very simple and yet it's very effective. The group discussions and putting all we are practiced in the lab in the theory is very good so we are able to understand all the terms and their meaning.

- Actually the note is guide can make me boring but the trainer can make me enjoy with the course with their style to conduct the course.
- Materials given are very limited as they want us to focus more on what they are saying rather than flip through the paper. And I agree in that. In a way, you have to really focus and jotted down your own notes. By doing 'reflection' of the 'yesterday' lesson, it keep us on toes so that we are always ready to answer / share what we learned a day before.
- What has been given is a lot. We just have to sit down & go through it and force ourself to start "method validation" without looking it is a "taboo".
- I think we still need the notes, at lease in summary or point form of important points.
- OK but presentation slide quick bored actually !! Maybe can put more picture or example.
- Overall its good
- Excellent of training method not only slide and presentation.
- The course method and resources are good enough to make me understand and follow the course.
- We don't get much supporting written document (hard copy) but we do get a lot in "soft copy. If the trainer could provide course reference document, it will be good.

BALANCE PRACTICAL AND THEORETICAL CONTENT

Balance between practical and theoretical content	Far too theoretical	Too theoretical III	Just right IIII IIII	Too practical	Far too practical
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- Maybe the practical can use our data, so that it will make more sense to us.

BALANCE LECTURES AND INTERACTIVE GROUP WORK

Balance between lectures and interactive group work	Far too many lectures	Too many lectures	Just right IIII IIII I	Too much group work I	Far too much group work
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AS A RESULT OF THE COURSE MY KNOWLEDGE, SKILLS AND SELF CONFIDENCE HAVE IMPROVED

Knowledge	Not at all	A little	Quite a lot IIII I	A lot IIII I
Skills	Not at all	A little II	Quite a lot IIII IIII	A lot
Confidence	Not at all	A little	Quite a lot IIII IIII	A lot III

PLEASE ANSWER THE FOLLOWING OPEN QUESTIONS

1. Please describe the overall relevance of the course to your work and your learning needs:

- We have to share our knowledge with other lab although they're not doing same analysis
- From this course, now I know how to do M. validation. B'4 this, I never doing MV and I don't know how to doing in the right step.
- The overall course is relevance to my work. Method validation is important in test / analysis in terms of knowing what we are doing, what do we want to prove and also the limit of detection of each controls.
- The overall of course is very relevant to my work. For the ISO17025 I have to do the method validation first. From method validation I have to determine the LOD by do for the control sample.
- In my line of work, I don't have the pressure to do validation since I'm not aiming to get accredited (ISO) but I'm trying to implement the good things about ISO in my lab/work. I learned a lot and I hope I can use the skill/knowledge in my research work.
- The course is really relevant to me as I am doing qPCR analysis. It answers a lot of my questions and uncertainty except measurement uncertainty.
- The course is really relevant in my own work / test and also can be apply to other lab / section in the centre. I really need to learn about methods validation to manage the quality in the centre I work.
- Method validation need. I get it and understand it very clear.; What is QA, QC, LOD, LOQ and it's important to understand that I didn't know it before.
- It very relevance of course to my work and my learning needs because what I need before is how to during method validation and finally I get it.
- Yes, the course are relevance to my work and will help me to improve the critical part in our accreditation application (ISO 17025)
- The method validation, concept and how to do it especially to find the LOD for my control in the test are very relevant. Know, I more confident and have clear vision to do method validation for my test.
- The course is very relevant to me personally as an analyst, auditor and laboratory manager. As an analyst I learned a lot of useful knowledge to improve my analysis or testing. I also learned about other participant's work in the department and this will prepare me in the future just in case I have to audit their lab.

2. Which topics of the course did you find MOST relevant and why?

- LOD – we must have tve and ve control in our analysis
- LOD – because from this course I know how and the way to find LOD for my test
- The know how to do the method validation. It's the most relevant one because to know how to validate our test means that we are able to produce quality results and reports.
- LOD is a topics that most relevant to my work/analysis because before I think the LOD is no need to do by my own lab just follow the manufacturer that given. LOD is very important to do for method validation. And now quite clear about concept of method validation. / Collaboration with other lab. / Aspect lab safety – such BO.
- The flow of validation. The why, how, control and prove, whether you go for accreditation or not, this is the basic thing you need to follow no matter you're doing a test or research.
- "Introduction to method validation & quality management". As it gives me an overall idea of what's going on and from there I can catch up things as I have understand the basic of the whole thing.
- The control and prove because before this I don't have the specific course on methods validation at all and just did the methods validation wrongly.
- LOD – very good and my information that I get because I actually don't know what is LOD before.; Method validation – I know the process that I can implement to our lab like what is repeatability, reproducibility, trueness and others.
- Method validation – because every method we used must be validate.; Safety lab – expose to safety lab for biological lab what we must good laboratory practice and what a bad.

- The method validation and verification because before this we are not clear how to do this thing in the important to us to get the accreditation (ISO 17025)
- The topics of “why, how, control and prove” are very relevant to me, because after this I know what to do / next step for my progress method validation and accreditation of ISO 17025: 2005.
- Method validation. This is very relevant for me to carry out my testing / analysis so that the results can be trust and proved. We regularly obtained negative results. Is this true. With the knowledge gain in this course we can be sure of our LOD and have more confidence when doing testing.

3. Which topics of the course did you find LEAST relevant and why?

- I think all the topic is relevant because they are all related to each other
- For me, all topics is relevant b'coz I learn more something new for my lab and myself. And there is no topics not relevant or least relevant.
- The course I found least relevant is the quantitative part in method validation. It's because for now, my test is mainly on qualitative only. It might be useful one day when I'm using RT-PCR but for now, I will try to put in practice on what are the important things to improve my test results and it's quality.
- Quantitative analysis because at my we didn't work with RT-PCR. It quite not clear for me to calculate the data and understand it too clearly
- The ISO thing. Even though we need to understand the ISO needs, and how it link / related to validation process, it took so much time.
- General introduction was too long.
- The ISO requirement is an important topic, but it is least relevant to me because I have attended a course with the accreditation bodies in Malaysia.
- RIKILT introduction – quick take a long time..
- No I think all of topics in this course are relevant what I need.
- No
- The topics of formula translation to Excel, because my type of test is no need to apply this formula.
- ISO / IEC 17025. I have attended a lot of courses in this subject and had written a quality manual for my organization. So basically I have a sound knowledge on this topic.

4. What are your 3 key lessons from this course and why are these so valuable to you and your work?

- 1) Need discussion with staff and the management to solve problems in analysis; 2) Lab analysis need tve and ve control to confirm our result; 3) we need training to improve our skills.
- 1) need more training; 2) we should have collaborative / contact to other lab to get more experience and knowledge; 3) should have someone to manage our lab.
- The three key lessons are: 1) open my mind in finding my information on method validation; 2) collaboration with other laboratory; 3) knowing what, why and how you want to do your work / test in laboratory.
- Reasons: 1) knowledge is important to keep us up to date on the latest method validation to improve the quality of the results; 2) It's not going to work if we want to do it alone. Getting help and work together with other laboratory is one of the step to proof our test analysis is correct ; 3) The most important thing is to know what, why and how do we want to produce a result which is quality.
- LOD, Lab safety, Collaboration. There thing very valuable for my work to reach the ISO 17025. Before this I never do the LOD because I didn't know the method I used to do the method validation by the right way. Because my lab just set up so I apply the thing with my new lab easily.
- 1) Validation is a process (cannot be singled out on its own); 2) The importance of working together (inter lab); 3) lab safety. All these are interrelated and important.

- 1) Method validation: what are the steps; 2) Controls: It's not just a positive & negative control. Many other controls you have to consider. 3) Limit of detection: this step is very important. All these 3 aspects are important and in order for me to really confident with my result & I can stand up / argue back with whoever that question my results.
- 1) The control in my test; 2) How to improve my test is being testing correctly and give the result correctly and reliable; 3) This course give me confidence in evaluating the work I've done during accreditation process.
- 1) Method validation process – what & how ; 2) LOD – what & how & why ; 3) Interpretation for technical requirement in ISO 17025 very detail.
- 1) Data interpretation such as from data formula transfer to excel and making a graph. 2) I can learn about how to do method validation. 3) I can practice about good laboratory practice for safety lab in biological lab.
- 1) During the course, not enough to know or remember the subject but we must understand, discuss and able to explain to others; 2) This subject matter is very technically and feel very lucky to attending this course and important and valuable to my work; 3) As internal auditor (ISO 17025) is good to me learn and know about other testing, which maybe I will audit them and I have the better understanding.
- 1) Management and technical requirement for ISO 17025: 2005 - I got clear knowledge for this requirement to get the accreditation; 2) LOD – I know how to find the LOD in my lab test; 3) Cooperation – The collaboration with related lab analyses.
- 1) The differences / types of LOD; 2) The different parameters that have to be carried out in method validation. E.g. specificity, accuracy, LOD, repeatability, reproducibility, trueness etc.(Not all parameters are mandatory to each test. But we have to choose the most appropriate and suitable to our needs. The same things goes with LOD determination); 3) The use of excel in counting / analyzing the data.

5. Please share which actions you will take after having participated in the course in relation to your work

- Do some experiment for the dilution of the culture to find the best LOD
- Explain to my staff about MV, how much important it is in ovr test; Try/doing LOD first and try it with my staff (doing together); Try/find out m.v. for my test.
- I will talk to my boss and my colleagues and explain what I've learn in the course, what we should do to get our ISO done. I will also start discussion with other laboratories in dong the interlab-testing and doing the LOD.
- Discuss what I have learn to my management to resolve problem such personnel, lab safety; Do experimental design for the LOD.
- I shall review my way of doing things and the first section that need to be work at is the 'control' part.
- Have a discussion with my boss & my lower staff on strategy of MV.; Next I would first do the specificity test.; Discussion with my colleague who is doing the same test as well.
- Prepare the LOD control in the test, collaborating with other labs in the job and assist my friends in the methods validation process to gain more experiences.
- Method validation part is the most important actually to prove our analysis but the data / experience about that before is very less.
- I will cooperate with other lab and doing intralaboratory testing and discuss our result.
- We will work together within 3 labs to conduct the method validation and method verification specify to our testing.
- I will share the information that I got from this course with my staff / colleague and then helping them and together we developed our method validation for my test / parameters.

- 1) I planned to work together with other participants who are doing the same analysis on method validation. We still focused on the determination of LOD, accuracy and specificity first. 2) Besides that, I also planned to invite one participant from other lab to my lab so that she can learn the determination of bacterial count in order to carry out her control LOD for her experiment. I noticed that she is not clear on how to do it.

6. What will be the first step(s) you will take within the coming 3 months?

- Have some collaboration with other lab or training on doing LOD (copies of the control – doing the dilution until get the lowest concentration.
- Keep contact, doing collaboration with other lab in some target / test
- Talk to my boss what we need to do what is important and what's need to be done.
- Train the others lab staff about method validation; Start to do the LOD by collaboration with each lab with same analysis.
- To discuss with my supervisor upon lab safety requirement
- Concentrate on specificity, LOD.; Do a lot of readings in order to understand more on the application of MV to my method.
- Prepare the LOD control and run the methods validation to gain data.
- Find our LOD control – never had before; Find the trueness of analysis ; More discussion between another lab.
- I will start with LOD for my analysis and also use of the control for get more information or data for my analysis.
- First to talk to our management our planning and to making a good planning or chart how to conduct this program.
- I will conduct a method validation for my test, do some cooperation with others lab and combine them to my work / test.
- Communication, planning and executing (hopefully)

FEEDBACK FOR FACILITATORS/TRANERS

What positive (good things) and constructive (things to improve) feedback do you have for Jeroen

- He try to solve our problems on LOD
- Good presenter and facilitator and have more experience in laboratory
- I love how Jeroen presented the theory and then he tried to put us in practice so we understand what's the whole presentation by doing group work and discussion. He is willing to take time and adjustment to achieve what we wanted during the course.
- Jeroen will try to make me all understand what he present by using example and try to help us on what we done on my lab.
- He can be strict and joyful in a matter of seconds! We need that when were taught a bored subject such as ISO etc.
- He is very informative & I can ask him almost everything. Constructive: skills of presentation.
- Clear explanation on the topics & very expert.
- Good things - he try so hard to solve our problems if we ask advice from him but he need to improve his English pronounce. I can't understand better when he talking because sometimes he talk is to slow and to louder.
- So far, he is a good presenter and he very knowledge in his field and easy to his explain everything what we need or what we not understand.
- 1) good listener and give comment; 2) He give the good suggestion and explanation even he not expert in certain field; 3) Expert trainer.

- Very knowledgeable in qPCR test especially in GMO's field.
- Very knowledgeable on qPCR; Easy, outgoing, pleasant, very clear explanation and presentation; Maybe can improved the knowledge on microbial / other biological validation method.

What positive (good things) and constructive (things to improve) feedback do you have for Stephanie

- Ready to teach/help when we needed
- She try the best very best way how to explain what we doesn't know; She should try to be facilitators (to give a talk) some topics, so we know she can be the "best" presenter, because in this course, she just help if we want to get explanation.
- Stephanie is very good in technical aspect and she can explain to the participants very clear and simple.
- She is good on technical and try to help.
- Smiley Stephanie! She's very reliable and very knowledgeable.
- Very informative and helpful. Constructive: skill of presentation;& should speak clearer.
- Opens our eyes to many ideas to problem solving in our job.
- Good example she show when we ask the practical example and very sweet trainer but I can't understand better when she talking.
- She also knowledgeable in her field and easy to her to explain what we do not understand.
- 1) Expert trainer; 2) Give better explanation and easy to understand.
- Always helpful and not hesitate to make me understand the technical part in my lab test.
- Very gentle, soft spoken; Knowledgeable on method validation in general.

What positive (good things) and constructive (things to improve) feedback do you have for Ingrid

- She know how to make us pay attention to the lecture.
- I think she has very experience to give presentation and the way she conducted the audience - class is very interesting.
- Ingrid makes the whole training course very fun and enjoyable. From getting our feedback after the previous training help us a lot in speaking up what we want in the course and what we still need them to help us.
- She try to make me all understand how, why we have to do in our lab. Make me enjoy with this course.
- Ingrid is the best facilitator I've ever met. She made the training interesting and enjoyable.
- She is very jovial. Which make the class lively & I think she is very good in coordinating the training.
- Making the course very interactive and we can understand knowledge in short time.
- Very energetic. Good trainer and I can understand clearly what the direction. Good body language.
- Ingrid is a happy go lady and I like her way and her explanation is very easy to me understand with her style. Lastly, I hope can be her participate next time in another course again. TQ.
- 1) Very experience training coordinator; 2) Friendly; 3) Very good to create better interaction and interactive way.
- Have a very good performance, energetic and know to handle the course and make it more interesting to follow.
- Very Irresistible, Interesting. Unique way of handling the training course (I learned a lot from her on this).; Able to make the participant to "speak" and "share" the information in a simple way.

This report describes the content, the approach used and lessons learned during the implementation of a capacity development programme to build the analytical capacity of laboratory staff of the Department of Fisheries (DoF) and the Ministry of Health (MoH) who are directly involved in the analysis and detection of forbidden substances in fish and fisheries products. Two training courses were implemented in 2011 in the Bio Security Centre in Kuantan, Malaysia. The first training course on 'Marine lipophilic toxins using LC-MS/MS' has been implemented in June and the second training course on on Stilbenes and Nitroimidazoles sample preparation and analysis with LC-MS/MS equipment was implemented in November, 2011. Through this knowledge transfer and laboratory enhancement the project contributed the laboratory's process towards getting accreditation under ISO 17025. The courses were implemented in partnership by Institute of Food Safety (RIKILT), Wageningen UR and Centre for Development Innovation (CDI), Wageningen UR.

More information: www.wageningenUR.nl/cdi

