UNSGM Designated Laboratories Workshop Report

Spiez, Switzerland
9 – 11 September 2018

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Contents

Acknowledgements 4
Executive Summary 5
1. Introduction 7
2. Review of exercises recently conducted or initiated 9
3. Interaction between investigation team and laboratories 15
4. Exploration of additional elements for quality assured laboratory evidence 17
5. Conclusions and next steps 18
Group photo 20

Acknowledgements

The fourth UNSGM Designated Laboratories Workshop took place from 9 – 11 September 2018 in Spiez, Switzerland.

The following Swiss Federal Departments made the workshop possible:

- Federal Department of Foreign Affairs
    - Directorate of Political Affairs, Division for Security Policy
- Swiss Federal Department of Defence, Civil Protection and Sport
    - Staff of the Armed Forces, International Relations Defence
    - Federal Office for Civil Protection, Spiez Laboratory

The organisers express particular thanks to Ralf Trapp (Disarmament consultant) and James Revill (University of Sussex) for their help in preparing this report.

Spiez Laboratory, the Swiss Federal Institute for NBC-Protection, is responsible for the content of the report. It does not reflect an official Swiss position.

Executive Summary

This was the fourth Swiss workshop organised by Spiez Laboratory on a functional network of trusted laboratories designated under the United Nations Secretary-General's Mechanism (UNSGM) to investigate allegations of the use of biological and toxin weapons. The initiative connects to the UNSG's Disarmament Agenda, which asks for adequate preparations to respond to any credible allegation of use of biological weapons.

The outcomes from previous workshops confirmed the desirability of developing a collaborative network of UNSGM designated laboratories that provides transparency and confidence in scientific competence, analytical skills, and quality assurance systems. Recent efforts have moved from conceptualisation and general discussions of benefits and requirements, to practical steps, most notably in the form of dedicated confidence building and quality assurance exercises.

In this year's issue of the workshop series, participants reviewed a number of recently conducted exercises, discussed the multifaceted interface between the investigation team and designated laboratories, and explored additional elements for quality assured laboratory evidence.

The laboratory exercises organised by Germany provide a framework for self-evaluation and improvement for participating laboratories. Twelve laboratories from ten Member States took part in a pilot exercise in which all participants were able to correctly identify the biological agent at the subspecies level. Additional tasks, aimed at characterisation of the biological agent, resulted in a more nuanced picture of capabilities of participating laboratories, especially when it pertained to whether evidence would hint at an outbreak of natural or deliberate origin.

A number of improvements for future exercises were suggested, and a range of issues that merit further discussion identified. This included broader geographical participation, recommendations for operating procedures, development of scenarios, sample transfers, chain of custody documentation, specialisation of laboratories, report writing, and data protection. Since some of these aspects are mission critical, a robust system needs to be developed step-by-step, while sensitising political actors and regulators to the importance of addressing these matters.

A range of notable benefits for participating laboratories was also identified, such as promotion of global collaborations, and the opportunity to benchmark capabilities. Further exercises were announced for the coming years with increasing levels of difficulty, progressing towards in-depth sample analysis that will move well beyond 'every-day' clinical diagnostics. These exercises would provide the UNSG, assisted by expert consultants, with an evidence-based data set for selecting bio-analytical laboratories possessing accurate capabilities for specific scenarios. In that sense, Member States are encouraged to nominate experts from their roster laboratories as consultants to the UNSGM.

Denmark in collaboration with Sweden started a project to strengthen UNSGM capabilities in the bio-analytical field through confidence building exercises aimed at specific detection and characterisation of a biological agent and its associated genetic markers using genome analysis. Results from the 60 participants showed that apart from Africa and South America, the capabilities are wide-spread in geographical and sector-wise terms. Therefore, several candidates may bear the potential to significantly expand the current roster of UNSGM bio-analytical laboratories.

The Organisation for the Prohibition of Chemical Weapons (OPCW) has already completed two toxin exercises. The second confidence building exercise included samples containing Ricin and Abrin, and used a scoring system for evaluating performance. Results obtained from 21 participating laboratories from 18 Member States indicated that good progress has been made since the

first OPCW toxin exercise. Nevertheless, areas for improvement were identified, since some participating laboratories reported a number of false positives and false negatives. Continued efforts in the field of toxins remain important, as current thinking is that an investigation involving a toxin would be deferred from the UNSGM to the OPCW and its Designated Laboratories.

Previous workshops already identified the interface between the investigation team and laboratories as an important element requiring further in-depth discussions. Participants recognised that UNSGM missions need to have intrinsic laboratory expertise to ensure that the laboratories' capabilities and sample submission criteria are clearly understood by the investigation team. All processes involved in sample analysis, from sample collection to reporting, must be robust so they can withstand political and legal scrutiny. Therefore, an analysis must follow forensic principles, such as strictly observing the chain of custody and ensuring sample identity.

This thinking lends support to the concept of using a hub laboratory as a direct link to the mission. To be able to fulfil such a coordination role, a hub laboratory needs to be impartial and nominated to the UNSGM roster, and it should meet agreed technical criteria. Since the context determines the concrete functions a hub lab will perform, it is important to remain flexible in terms of approach. Ultimately, it will be up to the Head of Mission to make any decisions on how a hub laboratory should support a mission structure.

Furthermore, workshop participants took a broader look at the issue of how the laboratory capability of the UNSGM has been evolving, and where more action is needed. Efforts are to be redoubled in attracting additional laboratories to broaden the geographical participation, and the network's performance needs to be tested on a regular basis through exercises. Member States that have taken on an active role in developing the laboratory capacity of the UNSGM need to work with other Member States to broaden political support for more transparency, share information on the laboratories they have nominated to the UNSGM roster, and encourage interaction between these laboratories.

There is significant common ground on what is required to strengthen the operational capacity of the UNSGM with regard to bioanalytical laboratories. Further developing a laboratory network through exercises and exchanges comes with significant benefits to Member States and their laboratories participating in such a process. This includes both intellectual growth and capacity development. Current awareness and general support for further development of the network must now be turned into commitments for sustained funding. Broader political engagement in support of this action would be one way to achieve this.

Spiez Laboratory is committed to support this bottom-up approach of roster laboratories and to engage in further developing common understandings for a laboratory network. Spiez Laboratory will therefore continue to provide a dedicated workshop platform for the sharing of results and experiences as well as to circulate new ideas and plans among the laboratories.

The fifth Swiss UNSGM Designated Laboratories Workshop is planned for 11 – 13 September 2019.

1. Introduction

This report presents the outcomes of the fourth Swiss workshop organised by Spiez Laboratory on a network of trusted laboratories designated under the United Nations Secretary-General's Mechanism (UNSGM) to investigate allegations of the use of chemical, biological and toxin (CBT) weapons. The workshop was attended by 54 participants from 15 Member States, the UN Office for Disarmament Affairs (UNODA), the Organisation for the Prohibition of Chemical Weapons (OPCW), the World Health Organisation (WHO), and the World Organisation for Animal Health (OIE).

The workshop series organised by Spiez Laboratory is part of a wider effort of UNODA and Member States to strengthen the operational capacity available to the international community to investigate allegations of the use of CBT weapons, particularly with regard to biological weapons for which a dedicated international organisation to conduct such investigations is lacking. As a "Member States' mechanism", the UNSGM depends critically on what Member States make available to it, and on what international partner organisations are able to contribute.

Strengthening the UNSGM is in line with the UNSG's disarmament agenda[1], which recognises that "*[in] order to be adequately prepared to respond to any credible allegation of use, the United Nations must have in place a dedicated institutional capacity. The Secretary-General therefore intends to work with Member States to establish an interim standing capacity to conduct investigations of the alleged use of biological weapons while seeking support from the General Assembly for a longer-term solution.*"

One particular challenge is the ability of the UNSGM to call upon bio-analytical laboratories to conduct sample analyses. Previous workshops have helped to clarify the role of laboratories nominated to the UNSGM in such investigations, and confirmed the desirability of developing a collaborative network of UNSGM designated laboratories to provide transparency and confidence in their scientific competence, analytical skills and quality assurance systems. This includes the necessary administrative and reporting procedures and the maintenance of an unbroken chain of custody throughout the investigation.

Previous meetings dedicated to UNSGM roster laboratories have been organised by Germany, Sweden, and Switzerland, with support from UNODA. The overall conclusions that have emerged from these meetings are as follows:

- Analyses of samples in the context of biological / toxin investigations include identification and comprehensive characterisation of the causative agent, which may contribute evidence to its origin and that could be of value for the purpose of attribution.
- Many highly qualified laboratories worldwide can, in principle, perform such analyses. However some biological agents of interest to the UNSGM are of little priority for public health laboratories, and, more importantly, there is no dedicated network of laboratories that maintains competence for UNSGM investigations – i.e. ability to meet the procedural requirements of the UNSGM, maintenance of in-depth analysis methods covering forensic aspects, assurance of quality standards, and fulfilment of reporting requirements.
- More collaboration is desirable between public health laboratories, academia, and other laboratories, to augment levels of standardisation and harmonisation of methods.
- Clarification is needed of what is meant by an unambiguous identification in the

[1] UN Secretary-General's Disarmament Agenda: "Securing Our Common Future - An Agenda for Disarmament", page 28 (pdf Version), https://www.un.org/disarmament/sg-agenda/en/.

context of a biological UNSGM investigation.

- The gold standard in identification of a biological agent is isolation, cultivation, and phenotypic characterisation. Since this may not always be achievable in a UNSGM investigation, alternative approaches will be required through the application of orthogonal complementary analytical methods.
- If samples are to be analysed, off-site analysis will be imperative for evidential reasons.
- Accreditation of methods and agreed acceptance standards are important.
- UNSGM roster laboratories must meet the highest biosafety standards.
- Next generation sequencing (NGS) methods are very promising but still rely on complementary analytical methods as well as approved bioinformatics pipelines for undisputed identification.
- Quality assurance tests are required to develop standards and criteria.
- Availability of curated databases that are comprehensive and accessible are currently a challenge.
- Additional methods are required to link an identified agent to its source / origin or delivery system.
- Reporting must be robust to withstand technical scrutiny in a political and legal environment.
- In addition to their role in off-site analysis, UNSGM laboratories need to make their expertise available to the investigation team to advise on such issues as sample collection, packaging and transfer.
- A roadmap is needed towards building a sustainable UNSGM laboratory network. This should include steps towards minimum requirements and criteria for assessments of laboratories nominated to the roster, evaluation criteria for analytical results, sampling guidance, reach-back concepts, curated databases, training packages, and practical exercises.

Building on these previous discussions, the fourth Swiss UNSGM Designated Laboratories Workshop focused on the following issues:

- Review of exercises recently conducted or initiated.
- Interaction between investigation team and laboratories.
- Exploration of additional elements for quality assured laboratory evidence.

This agenda reflected the progress made since the third workshop in 2017: Moving away from purely conceptual discussions, starting practical work and fostering interaction between laboratories interested in contributing to the development of such a trusted UNSGM laboratory network.

A requirement identified in previous meetings was the need to facilitate communications between the laboratories that participate in these discussions. To this end, Spiez Laboratory has set up a SharePoint to provide access to relevant documents and pertinent information.

2. Review of exercises recently conducted or initiated

Background

The UNSGM Guidelines and Procedures (A/44/561) direct the UN Secretary-General, assisted by expert consultants, to carry out inter-laboratory calibration tests to evaluate validity and accuracy of analytical methods used by the roster laboratories.

The goal of such tests is to demonstrate the competence of individual laboratories nominated to the UNSGM for detection and identification of known CBT agents, and to evaluate their capabilities to detect the presence of other ("unknown") agents.

It is questionable whether sufficient laboratories have already been nominated to the UNSGM roster, both in terms of competencies and geographical spread. For example, some Member States have opted for an *ad hoc* nomination process whereby they would nominate laboratories for a particular investigation depending on the scenario. This creates difficulties with regard to predictability and planning, since there is a lack of transparency concerning the capabilities of these laboratories.

This lack of specific evaluation of individual competencies, capabilities and quality assurance systems currently applies to all laboratories nominated to the UNSGM. Dissimilar to the OPCW system, UNSGM roster laboratories in the biological field have:

- No regular dedicated quality assurance tests.
- No dedicated laboratory network.
- No coordinator for managing collaborations, organising quality assurance tests, and developing guidance.
- No criteria for minimum analytical requirements including standard or recommended operating procedures.
- No criteria for interpretation of analytical results.
- No agreed guidance for logistics, sample distribution, and sample transfers.

The third Swiss UNSGM Designated Laboratories Workshop witnessed the announcements of a German project on the analysis of bacteria, viruses, and toxins, and a Danish-Swedish project on genomic analysis. In addition, the OPCW continued with a confidence building exercise on toxin analysis. This fourth workshop started with a review of the results of these initiatives.

German contribution to strengthen biological reference laboratories for the UNSGM

In August 2017 Germany started the project 'RefBio 2017-2020' to create a better understanding about the roles and capabilities of UNSGM roster laboratories, to provide a framework for self-evaluation and improvement through exercises, and to define the minimal and optimal analytical requirements that UNSGM roster laboratories should meet.

A pilot phase from August to December 2017 involved a workshop and a first external quality assurance exercise (EQAE). The workshop in October 2017 discussed the interpretation of laboratory results, minimum analytical requirements, and the planning of the pilot EQAE. The main phase has an allocated funding of EUR 1.4 million, which will cover staff costs and the conduct of 8 workshops as well as exercises with gradually increasing difficulty in the fields of bacteriology, virology, and toxinology. At a workshop in June 2018 results of the first EQAE were reviewed and future exercises discussed.

The 2017 pilot exercise used inactivated *Francisella tularensis* as the target agent. Twelve laboratories from ten Member States participated in the exercise which involved two distinct levels: (a) identification (or ruling out) of the target, and (b) characterisation (taxonomic classification, virulence genes, antibiotic resistance genes)

combined with specific questions (identification of peculiarities indicative of genetic modifications, hints at natural or deliberate outbreak, and whether the strains in positive samples were identical or different). The exercise organisers provided data entry forms for reporting to facilitate a common approach. Each laboratory received two sample sets, i.e. three clinical and three environmental samples, and each set included a negative control sample.

Laboratories employed a variety of analytical methods, including quantitative PCR (qPCR) and next generation sequencing (NGS), both of which performed best. All laboratories were able to identify / rule out the target, correctly identify the subspecies, and there were neither false positive nor false negative identifications.

Correct responses to the additional tasks (identification of the subclade and the strain, antibiotic resistance genes, virulence genes) varied between 50 and 92 %, the latter reflecting a higher concentration of the target in the positive environmental sample. The responses to hints about whether the outbreak was of natural or deliberate origin varied as well.

Improvements for future EQAE could include more elaborate reporting templates and integration of chain of custody information into the data entry forms, the provision of information on the use of accredited methods, and a working definition of identity when comparing genomes.

The following parameters of the pilot test will be retained in subsequent exercises: use of one target per test, provision of information about the target in advance of the exercise, specification of tasks, target characterisation, assessment of the laboratories' screening capabilities, and scenario-specific questions.

A range of issues was identified that requires further discussion:

- How to broaden geographical participation of bio-analytical laboratories?
- What are the minimal and optimal capabilities of bio-analytical UNSGM laboratories?
- How to draw recommendations on laboratory proficiency for UNODA?
- Which scenarios should be covered?
- How to link up with other relevant projects and draw common conclusions?
- What are the logistics for sample shipment and dissemination?
- How to document the chain of custody?
- How to assess the impact of different methods on analytical outcomes?
- How to involve highly specialised laboratories that do not cover the entire panel of agents?
- How to write the report?
- How to handle data protection within a network of bio-analytical laboratories?

For broader geographical participation:

- Roster laboratories could be contacted by UNODA and the EQAE provider to encourage participation.
- Direct communications could be established between EQAE provider and roster laboratories.
- Member States could be encouraged to take account of recommendations for minimal requirements (once agreed), and to review their nominations of analytical bio-laboratories accordingly.
- Training should be made available to improve laboratory capacities.

With a view to minimal requirements, Member States could be encouraged when nominating laboratories to the UNSGM roster to take into account that such laboratories should:

- Have methods and infrastructure in place to cultivate high-risk target bacteria and viruses.
- Be able to receive and send infectious material.

- Have validated methods in place for analysis.
- Have methods established to confirm results up to an unambiguous level (if possible).

The first EQAE showed the necessity that experience for in-depth sample analysis beyond 'every-day' clinical diagnostics is available to roster laboratories.

Considering data protection, results were only provided in anonymised form. There are however plans to publish some general outcomes in agreement with the participants. In the longer run, additional measures to protect confidentiality should be considered, such as:

- A secure internet platform to exchange data.
- Development of a Consortium Agreement to be signed by participants.
- Non-Disclosure Agreement to be signed by involved parties including UNODA and expert consultants.

Overall, feedback by participants confirmed that the project is on the right track. The project engages with laboratories that have been nominated to the UNSGM roster or are likely to be nominated *ad hoc* by Member States depending on the scenario. The test confirmed the desirability of setting up a network of bio-analytical laboratories serving the UNSGM. To this end:

- Annual EQAE with increasing levels of difficulty will be organised for bacteria, viruses, and toxins during the coming years.
- Benefits for participating laboratories include access to expert knowledge, self-evaluation, and identification of areas requiring improvement.
- The benefit for the UNSGM is further operationalisation of the UNSGM Guidelines and Procedures through the conduct of "inter-laboratory calibration studies" for bio-analytical laboratories.
- This would provide the UNSG, assisted by expert consultants, with an evidence-based data set for selecting bio-analytical laboratories possessing accurate capabilities for specific scenarios.
- Added value with respect to other relevant projects should be identified.

Participating laboratories also experienced distinct challenges. In some cases, sample shipment was delayed because of shipment documentation issues and varying levels of proficiency of the shipping companies. Depending on the circumstances, sample shipment may be mission critical. This underlines the need to test all steps in exercises using different scenarios. Apparently, despite nine years of experience in Europe with conducting live agent EQAE, uncertainties remain with regard to critical steps of sample shipment. The OPCW has the advantage of having a dedicated regulation for sample transfers in place, which gives the Director-General authority to certify samples so they can be shipped in accordance with this regulation. Correspondingly, the UNSG should be given similar authority related to UNSGM investigations. Also, Member States may consider using general licensing procedures to facilitate such transfers. The system needs to be developed step-by-step, and it will be essential to sensitise political actors and regulators to the importance of addressing this matter.

A second issue was terminology, since participating laboratories were tasked to report peculiarities indicative of the use of the identified agent as a biological weapon, and to assess whether the identified strains were identical or not. These are tasks that some laboratories were not familiar with, nor were they comfortable to provide answers in absence of clear definitions. For future exercises it will be important to clarify such issues at the outset. This could include tentative practical guidance.

Furthermore, it is crucial for laboratories to comprehend that reports are expected to remain technical in nature, and that the drawing of any conclusions must be left to the investigation team itself. This is particularly important in the event of discriminating between natural and deliberate out-

breaks. Similarly, laboratories need to be aware that they are to substantiate their findings with analytical evidence. They must be prepared to disclose the use of any proprietary databases and of the reference data used in their analysis. This may pose challenges since some of these data may be classified.

Another issue was the level of confidence in the test results that laboratories were asked to report, since sample amounts were limited. Using cultivable material would prevent this kind of issue. However, it would also mean that all participating laboratories must be able to deal with live agent samples in a safe way.

Finally, data analysis and interpretation was recognised as a challenge. Especially important is the availability of and access to curated databases as well as subject matter expertise. Laboratories are encouraged to share expertise and reference data, to develop curated databases, and to bolster networking. In a similar vein, standardisation of methods and benchmarking would be useful.

A number of notable benefits for participating laboratories were identified:

- Promotion of global collaborations, with a view to sharing bio-resources, and gaining access to curated databases and subject matter expertise.
- Opportunity to benchmark capabilities of the participating laboratory, which augments confidence and assists in identifying critical gaps and needs for further development.

With regard to future EQAE, organising post-exercise sharing sessions was deemed valuable as a means of extracting lessons-learned.

To broaden geographical participation, opportunities exist to link the UNSGM to regional measures, such as the ASEAN CBR initiative that intends to establish a regional network of CBR experts. Such regional networks can help with further developing the UNSGM laboratories network.

As in the early days of developing environmental sample analysis approaches in the OPCW, demonstration of capabilities and strengthening confidence stand at the centre of bio-analysis exercises. It is reasonable to assume that the UNSGM will need a wide variety of bio-analytical capabilities. Consequently, the network would have to be adaptable to many different scenarios and be able to provide specialist expertise in a whole range of biological agents. This squaring of generalist and specialist aspects is however something that cannot necessarily be addressed by individual laboratories. More thought is needed on how to involve a range of laboratories for a particular analysis.

There is concern that the UNSGM lacks a coordinating centre for bio-analytical laboratories similar to the OPCW Laboratory. Such a central focal point is important for managing proficiency tests / EQAE, and the development of the network as a whole. Such a coordination centre could be built up over time, and a step in this direction could also be to encourage Member States to nominate experts from their roster laboratories as expert consultants to the UNSGM.

Confidence building exercise organised by Denmark and Sweden

A second contribution to strengthen UNSGM capabilities in the bio-analytical field was a dry-lab test organised in April 2018 by the Technical University of Denmark, in collaboration with FOI Sweden, the European Bioinformatics Institute and UNODA. The US Department of State provided funding. This first of a total of three genomic exercises focused on the identification of the target species and genomic modifications of virulence factors. Invitations for participation were sent through a range of existing WHO, EU and global networks as well as through UNODA to current roster laboratories. The 60 participating bioinformatics entities were from varying institutional backgrounds, from defence, microbiology, veterinary and food safety, and public health.

The confidence building exercise aimed at correct detection and characterisation of a biological threat and its associated genetic markers using genome analysis. Datasets for 36 single genomes (27 non-modified and 9 modified) were provided for analysis. Participants were asked to identify the species, identify genome modifications, and characterise the bacteria with regard to any modifications.

A questionnaire was used to record a database of returns from the participants, and a scoring system was applied to rank performance. Whereas 92.5 % of the participants correctly identified the genome to species level, subsequent tasks showed a substantial decrease in performance. Generally, lower scores correlated with a more limited tool range available at the corresponding entities. Also here, terminology was an issue leading to misunderstandings of the tasks.

Final scores showed that across all data sets, 16 out of the 60 participants scored above 80 %, 35 between 50 and 80 %, and 9 scored below 50 %. Among the top scorers were participants from Europe, Asia, North America and Oceania, and from all types of institutions. This first exercise showed that apart from Africa and South America, the capabilities are wide-spread in geographical and sector-wise terms. Therefore, there is evident potential for expanding the roster of UNSGM bio-analytical laboratories.

In future exercises, the time span for analysis will be extended to two months, since participants of some countries had difficulties downloading the considerable data volumes due to connectivity or security issues. In addition, the response submission will be simplified to render the process faster and easier, and terminology delineating the tasks will be reviewed to render it less prone to subjective interpretation. The data file quality will be reviewed upfront, and a list of relevant bacteria will be provided to guide participants.

There were suggestions, as with the previous project, to consider organising post-exercise meetings to share experiences among participants and the exercise provider.

OPCW confidence building exercise on toxin analysis

A third area where progress was reported related to toxin analysis. The OPCW's initial focus had been on establishing its network of Designated Laboratories for the analysis of environmental samples. Subsequently, it expanded this with a second set of laboratories separately designated for the analysis of biomedical samples. This type of analysis called for new analytical capabilities, for example methods for the analysis of protein adducts. So far, the focus of OPCW proficiency tests has been on small molecules. In contrast, Designated Laboratories for biomedical sample analysis need to be able to analyse proteins and peptides, which require other techniques.

Toxins have never been included as spiked chemicals in OPCW proficiency tests. The OPCW is now beginning to prepare for the designation of laboratories for toxin analysis, following the same general approach it used for environmental and biomedical samples by conducting a series of confidence building exercises. This will initially assist laboratories to assess and improve their capabilities, and will be followed by clarification of acceptance criteria for designation, ultimately leading into formal proficiency testing schemes.

The OPCW has now completed two toxin exercises, a third one will be conducted in December 2018. The second confidence building exercise included samples containing Ricin and Abrin, and used a scoring system for evaluating performance. The choice of these two toxins as targets took account of their similarity in effect as well as the fact that Ricin is a Schedule 1 chemical, whereas Abrin is not included in the Schedules. The objective was to demonstrate whether the laboratories were able to correctly identify Ricin in the presence of Abrin.

Twenty-one laboratories from eighteen Member States participated in the exercise. The results indicated that good progress has been made since the first OPCW toxin exer-

cise. Nevertheless, areas for improvement were identified, since some participating laboratories reported a number of false positives and false negatives.

Subsequent exercises will likely look at the detection of Saxitoxin. Whether certain toxins currently not listed in the Schedules should be included in exercises remains to be decided. The OPCW is planning more confidence building exercises before it may consider moving towards formal proficiency tests. In any event, the competence to conduct toxin analysis may not necessarily result in yet another designation scheme, but could perhaps be integrated into the existing schemes.

The OPCW is also working on improving its forensic capabilities but due to limited laboratories' capacity there are constraints to the number of exercises they can partake in. These capacity limitations also raise the question of how to avoid duplication of exercises organised elsewhere but involving the same laboratories, or similar targets. At the same time, molecules such as Saxitoxin deserve more attention. In particular, there is a need to develop and maintain analytical libraries for such types of agents. In addition, OPCW experience suggests that the reporting requirements for these types of analyses should be reviewed.

With regard to the UNSGM, current thinking remains that if an incident involving a toxin was to be investigated, this would be deferred to the OPCW and its Designated Laboratories.

3. Interaction between investigation team and laboratories

The second segment of the workshop discussed the interaction between the investigation team and designated laboratories. This topic had emerged in previous discussions as an important difference to the way the OPCW system has been set up. In the OPCW, Designated Laboratories do not interact with inspection teams and guidance is provided by the OPCW Laboratory.

The UNSGM Guidelines and Procedures allow roster laboratories to play a broad role through presenting methodologies for sample collection, transport, and analysis, among others. Past UNSGM workshops and exercises have clarified that UNSGM missions need to have intrinsic laboratory expertise. The partnership between laboratory and field team is important. This ensures that sample submission criteria and the laboratories' capabilities, such as regulations of high-containment laboratories that limit the types of samples they can receive, or forensic awareness, are clearly understood.

All processes involved in sample analysis, from sample collection to reporting, must be robust so they can withstand political and legal scrutiny. This includes:

- Correct sample labelling to guarantee the sample identity.
- Sample identity must be cross-referenced to each sample data sheet.
- Sample data sheets demonstrate submission requirements for the roster laboratory and accompany all samples submitted.
- Chain of custody to account for the sample from collection point to laboratory through analysis and reporting must be unimpeachable.
- Analysis must follow forensic principles – each method used has to be validated, scientifically accepted, and reviewed by experts.

There is a whole range of issues to be considered, including logistical issues, when it comes to weapon remnants where ammunition would need to be drilled. Questions also arise about sample triage of potentially mixed samples that could contain hazardous material other than biological agents. Other questions include: whether sample preparation should be done before sample shipment, issues related to the removal of samples from contaminated zones, and sample packaging. The requirement to split and share sample aliquots necessitates awareness about terminology, i.e. what is meant by sample identity in the case of split samples. Regulatory and logistical requirements related to sample shipment need to be clearly understood, and shipment conditions must be such that the integrity of the samples is preserved.

All these considerations reinforced the previous conclusion that laboratory expertise must be present within the mission. They also lend support to the idea of using a hub laboratory from the UNSGM roster as direct link to the mission. A hub laboratory would be at the mission's disposal, to manage and support such essential issues as chain of custody, sample logging, expert advice to field investigators, exhibit triage, sample storage, movement and shipment to laboratories, and impartiality of analysis.

To be able to fulfil a coordination role, a hub laboratory needs to be impartial and nominated to the UNSGM roster, and it should meet agreed technical criteria as well as political considerations. Specifically, it should:

- Meet certain quality standards, such as accreditation to ISO standard 17025 and national accreditation to forensics standards.
- Have experienced and qualified staff.
- Adhere to the required biosafety standard.

- Be experienced in the analysis of bacteria, viruses, and toxins when the nature of the causative agent remains uncertain or unknown.
- Have procedures and processes for laboratory decontamination and quality assurance in place to reduce the risk of cross-contamination.
- Have established processes for importing and transporting potentially pathogenic or hazardous biological samples in accordance with applicable regulations, which includes trained staff for sample packaging in accordance with IATA regulations.
- Have a technical arrangement in place with the UN regarding the protection of confidentiality.
- Have good international working relations.
- Have a track record in report compilation and assessment.
- Be able to prioritise work when a UNSGM mission is established.
- Have funding and staff available for such additional work.

The concept of including a hub laboratory in a UNSGM mission needs further detailed consideration. There are many factors that speak in favour of this approach:

- Avoid overloading roster laboratories with samples during an investigation, since there should not be a limit on the number of samples taken as there may not be another chance to access the location – instead, samples can be prioritised for analysis.
- Developing a tailored sampling and analysis plan that will be compatible with the capabilities, requirements, and limitations of the receiving laboratories.
- Ability to provide real-time context-aware laboratory advice to the investigation team.

Another question is whether such a hub laboratory should perform certain functions, such as cultivation or sequencing, or whether its role should be strictly limited to administration and technical support, given that its independence and integrity need to be beyond reproach. Furthermore, the hub laboratory will likely have to be accessible to members of the investigation team, and has to be in a position to accommodate international observers in order to demonstrate transparency and for purposes of verifying the chain of custody.

In any event, it will be important to train the entire sampling process and all of its interfacing steps, from sample collection to analysis and reporting, in a holistic systems approach. Past United Nations Special Commission (UNSCOM) experience with regard to laboratory involvement, sample planning and management, and reach-back should be studied to extract lessons for the UNSGM. OPCW field experience has also shown that secure voice and data communications is essential. To conduct such training, funding sources need to be mobilised.

The context of an investigation will significantly influence the ability of a mission in the field to take account of any laboratory advice it receives, including from a hub laboratory. Access limitations in space and time when operating in a conflict zone, the potential inability to re-visit certain locations, and the pressure on the mission to present results as early as possible are all factors that show how important it is to maintain flexibility in any chosen approach. The context will determine what is feasible, expectation management will be critical, and it is the Head of Mission who will bear responsibility for any decisions taken.

Finally, there are political considerations with regard to how the concept of a hub laboratory fits with the UNSGM Guidelines and Procedures in which reference is made repeatedly to a "secure work area". In the end, the Head of Mission is the one responsible to the UNSG for the implementation of the investigation, and a hub laboratory can only ever be a mission support structure.

4. Exploration of additional elements for quality assured laboratory evidence

The concluding segment of the workshop took a broader look at how the laboratory capability of the UNSGM has evolved, and where more action is needed.

Member States have to date nominated some 40 laboratories to the UNSGM roster, but little is known about their capabilities and capacities. External quality assurance exercises have now begun and additional exercises are being planned. Discussions on quality standards, evaluation criteria, and procedures are progressing well. More work is needed to address sampling procedures covering the entire chain from sample collection to analysis and reporting. The structure and functioning of the UNSGM laboratory network starts to take shape.

More efforts are needed to attract additional laboratories, and the network's performance needs to be tested. Options include table-top exercises, tests of different elements and interfaces, and field exercises integrating laboratory support and analysis.

At the same time, some experiences can be extracted from existing systems applied by various national and international authorities and organisations. With regard to sample transfers, new opportunities could arise from joining with the UN Department of Operational Support. This new, client-based entity provides hazardous material transport. With guidance from Member States' initiatives it could become a valuable partner in organising sample transfers.

Interaction between investigation team and laboratories will be important in the training of sampling and underlines the benefit of joint exercises. Several Member States and organisations have procedures in place that in many cases have been adapted from established military procedures. Differences in the details of such national approaches exist. In the UNSGM context, general guidelines should be complemented with a detailed process / methods description to avoid surprises when samples arrive at UNSGM roster laboratories for analysis. This detailed process could be transformed into recommended / standard operating procedures to achieve credible analytical results.

UNSGM investigations may also have to deal with 'unknown samples', in which case their analysis will require a very good understanding of the capabilities of different roster laboratories to ensure that the appropriate ones are selected for analyses. UNSGM expert consultants could provide advice for the selection of suitable laboratories.

With regard to the geographical representation in the UNSGM laboratory network, it was recognised that many developing countries today lack the competence and capacity required. Broader geographical participation is clearly needed, however there are limits to what can be achieved with capacity building. This underlines again the desirability to define minimum analytical capabilities that all laboratories nominated to the UNSGM roster ought to meet. Roster laboratories that meet these minimum requirements should be encouraged to take part in EQAE. Furthermore, there is a need to have independent quality assurance bodies assessing the conformity of participating laboratories.

There are, however, limitations to the amount of information that UNODA holds on the different laboratories nominated to the roster. Member States have been reluctant to provide additional information on the capabilities and competencies of their laboratories, or to share certain information with others. It is therefore important that Member States that have taken on an active role in developing the laboratory capacity of the UNSGM, work with other Member States to gain political support for more transparency, share relevant information on the laboratories they have nominated to the UNSGM roster, and encourage interaction between these laboratories.

5. Conclusions and next steps

The efforts to develop a network of UNSGM bio-analytical laboratories has moved from conceptualisation and general discussions of benefits and requirements, to practical steps involving confidence building exercises, the discussion of evaluation and performance criteria, and eventually the development of recommended or standard operating procedures. There is sufficient common ground and shared perceptions of what is required to strengthen the operational capacity of the UNSGM with regard to bio-analytical laboratories. There is also a growing appreciation that developing such a network through exercises and exchanges comes with significant benefits to the Member States and their laboratories participating in the process. This includes both intellectual growth and capacity development.

The work on laboratory analysis is taken forward in the broader context of developing capabilities along the entire chain from sample planning to sample collection, transfer, storage, analysis, and results reporting. Furthermore, it is becoming apparent how laboratory work may be combined with the training of roster experts in table-top and field exercises.

New ideas such as the possibility of assigning a hub laboratory to a UNSGM mission have been substantiated, leading to a better understanding of the implications, requirements, benefits and potential limitations of such an approach. Ideas were also circulated that aimed at broadening geographical participation in the evolving network.

To make this process sustainable, it is important to broaden the political engagement in support of this action. Member States must be informed about the progress that has been made, so that they may recognise the benefits to themselves and their laboratories as well as of the increased capacity available to the UNSGM. Permanent Representatives to the United Nations could be mobilised to marshal political support in their respective countries.

The development of the UNSGM laboratory network connects to the UNSG's Disarmament Agenda. This creates an opportunity to strengthen the support and commitment to this action.

This awareness and general support for further development of the network must now be turned into commitments for sustained funding. For example, it would be desirable to engage in more focused 'expert group'-like work before the next workshop, and also to continue bringing together the expert consultants nominated by Member States to the UNSGM. It was discussed that the German project could serve as a coordination hub for selected issues, and there was the idea of setting up an Advisory Board to this effect. Switzerland is committed to further developing common understandings on a laboratory network. Therefore it will continue to provide a dedicated workshop platform for sharing results and experiences as well as circulate new ideas and plans among the laboratories involved in the development of the network.

The experience of the past years has shown how important it is to maintain this bottom-up approach, driven by the laboratories themselves and aiming at tangible, practical results. As the plan to develop the network is gaining acceptance, it is becoming clearer what requirements will need to be met, and where gaps exist. This workshop showed the progress made but also highlighted specific areas that deserve further detailed discussions and technical work:

- Aiming for a broader geographical representation of laboratories that take part in these discussions and practical exercises.
- Development of plans and funding mechanisms for future EQAE to establish best practices and quality assurance.
- The concept of a hub laboratory in UNSGM missions.

- Issues related to the shipment of samples and the chain of custody, including a possible engagement with the UN Department of Operational Support.
- Development of Recommended Operating Procedures, and reporting formats and criteria.
- Access to curated databases and reference materials.
- Evaluation methodologies for laboratory outputs.

The workshop participants confirmed the utility of this workshop series organised by Spiez Laboratory. The fifth Swiss UNSGM Designated Laboratories Workshop is planned for 11 – 13 September 2019.

Group photo


Fourth Swiss UNSGM Designated Laboratories Workshop
09 – 11 September 2018, Spiez, Switzerland
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Confédération suisse
Confederazione Svizzera
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