

UNSGM Designated Laboratories Workshop Report

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Federal Department of Defence, Civil Protection and Sports DDPS
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Contents

Acknowledgements	4
Executive summary	5
1. Introduction	7
2. Unambiguous Identification – Laboratory Perspectives	9
3. Investigation Mandate	12
4. Reporting of Investigation Results	15
5. Consolidation – Progress and Achievements	17
6. Towards a SGM Network of off-site Biological Laboratories	19
Group photo	20

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Executive Summary

This was the second of a series of workshops that Switzerland is organising with the objective to establish a network of laboratories for the analysis of samples in relation to biological weapons. The laboratories of this network have been nominated to the laboratory roster under the United Nations Secretary-General's Mechanism (SGM) to support an investigation of alleged use of biological weapons. The workshop discussed unambiguous *identification* of a causative agent, the role of a *mandate for analysis* and the *reporting of laboratory results*.

The *identification* of a causative agent is a critical element for an investigation. The respective laboratory data will support the mission's findings and contribute to a final assessment. Notwithstanding that laboratory results are only part of the overall evidence, specific requirements must be met to support an identification. These include multiple orthogonal analytical techniques meeting established acceptance criteria, laboratory accreditation to internationally accepted standards and method specific quality assurance measures. Paramount is an unbroken chain of custody for samples from the start of forensic evidence gathering as well as the subsequent evidence handling. Related training is a must for members of the investigation team and for off-site laboratories because forensic standards cannot be retrofitted. The accreditation of all the relevant analytical methods at each of the designated laboratories may not be feasible due to resource limitations. Therefore a patchwork of laboratories of which specific capabilities are well known and documented should be created for the SGM. Such a portfolio will also help a mission to adapt to changing circumstances as any mission must expect the unexpected.

An unambiguous identification through cultivation may in many scenarios no longer be possible. Therefore, it may be appropriate to characterise an identified agent in a given mission context and narrative. The laboratory results are assessed based on probability and relevance of a particular method in such

context. This requires developing a scoring system for laboratory methods. The aim would be that the cumulative score for all methods used in characterising an agent would lead to a scientifically satisfactory level of confidence for an identification. Establishing such a scoring system is an iterative process that must be tested with practical examples.

The *mandate for analysis* is to be understood as a set of instructions and guidelines to off-site laboratories, bearing in mind the need for flexibility depending on the mission context. In particular at the beginning of a mission, the required laboratory experience may not yet be known. The first objective for off-site laboratories is to identify a causative agent. This is followed by a characterisation of the agent which can help assess whether an incident was caused by natural disease outbreak, accidental release or a deliberate biological weapons attack. Should laboratory results alone not permit a final conclusion, they will be essential evidence to support such a conclusion.

If attribution is part of the objective of a mission, a further task for off-site laboratories may be to extract possibly relevant information from the sample. Attribution however may require different types of analysis to link a causative agent to a source or a delivery system to a particular actor. During the conduct of a SGM Mission it is important to manage expectations of stakeholders regarding the information an investigation and its laboratory results can yield, and how much time may be required to establish such information.

OPCW Designated Laboratories perform their off-site analysis independently and without interaction with the inspection team. Contrary to this, laboratories in a biological investigation may have to play a more interactive role with the team, which should be practiced in exercises. Embedding an expert laboratory capability in every investigation team is thus critical to ensure the team's independence in its decision

making. The OPCW also has a central laboratory hub managing sample dispatch to off-site laboratories. For an investigation of alleged use of biological weapons this gap may have to be filled. An on-site capability has clear limitations, not only but also in relation to biosafety. An alternative solution would be to task a designated off-site laboratory with the functions of a central laboratory hub.

The *reporting of laboratory results* as part of the report of an investigation is a critical element to support the findings presented by the investigation team. The correct interpretation of all data collected and an explanation of what can be concluded from this evidence for a non-technical, political audience is crucial for mission success. The report must be robust to withstand technical scrutiny in a wider political and legal context. Obtaining legal guidance during drafting may therefore be necessary. The content of the report must strike a balance between being understandable for a lay audience and providing sufficient technical detail to demonstrate that laboratory methods used were appropriate and validated, leading to quality controlled and coherent results. Furthermore, the reporting of laboratory results should include any unusual or unexpected findings.

In *conclusion*, the gold standard in analysis remains isolation and cultivation of a pathogen to confirm the agent alive. This however is only possible if respective samples can be collected in due time. Working with such samples affects sampling and sample handling procedures as well as shipping conditions.

Looking ahead, the absence of a capability portfolio for laboratories makes it difficult for the UNSG to select laboratories with the required capabilities in case of a request for an investigation. This should be addressed with some urgency.

Switzerland will hold a third workshop in June 2017 based on strong support voiced by workshop participants to continue this process and following indications for individual engagement by several workshop participants. In preparation for the next workshop practical steps must be initiated. These include developing a scoring system for laboratory methods and criteria for reporting the results of such methods, both to be tested in a table-top study. In parallel, preparations must commence by parties willing to contribute to inter-laboratory testing to build confidence among laboratories.

1. Introduction

The United Nations Secretary-General's Mechanism (SGM) is an important instrument of the Secretary-General to investigate allegations of use of chemical, biological or toxin (CBT) weapons for the international community. The second workshop in a series organised by Switzerland was aimed at strengthening the roster of designated laboratories that would support allegations of use of biological weapons. The first workshop in this series was held in November 2015. The SGM is an essential part of effective implementation of the norm against chemical and biological weapons and at the same time serves as a deterrent against their use. The lack of an institutional framework and resources with regard to biological weapons disarmament makes the mechanism particularly important.

The Spiez Laboratory SGM workshop series complements activities organised by other countries as well as by the UN Office of Disarmament Affairs (UNODA) and the Organisation for the Prohibition of Chemical Weapons (OPCW). The 2013 UN Mission to investigate allegations of the use of chemical weapons in Syria was the first such mission in over 20 years and as a result a lessons learned process was undertaken by UNODA to improve the SGM's operational capacity. One challenge with regard to investigations of alleged uses of biological weapons is the ability of the SGM to call upon off-site laboratories to conduct analyses in support of an investigation.

The previous initiatives by UNODA, the OPCW and several Member States all have helped to clarify further the requirements of a SGM investigation concerning the alleged use of biological and toxin weapons. Operational gaps and weaknesses as well as existing experiences and capacities have been identified. Notably, off-site analysis performed by selected laboratories is crucial to such investigations. The discussions so far have underlined the importance of providing transparency and confidence in the scientific and technical skills as well as the

quality systems applied by these laboratories. This includes areas such as validation of methods, standards and reference data; the use of robust quality assurance systems; rigid adherence to the necessary administrative and reporting requirements; and the maintenance of an unbroken chain of custody.

Building on these previous discussions, the second SGM Workshop in Spiez focused on three particular issues:

1. What would be considered an unambiguous identification by an off-site analysis laboratory in the context of a SGM fact-finding mission?
2. What would a mandate look like and how can it be fulfilled by an off-site analysis laboratory?
3. What would be contained in a report from an off-site analysis laboratory in order to meet full scientific and political acceptance?

These questions reflect the simple truth that although much investigative and diagnostic work can be done in the field – and more will be possible in the future given the advances in science and technology – independent off-site analysis will remain essential for an investigation.

But they also reveal some of the differences to investigations of an alleged use of chemical weapons, for which the OPCW has set up a network of designated laboratories that regularly demonstrate their competence for off-site analysis in inspections and investigations conducted pursuant to the provisions of the Chemical Weapons Convention. In biological investigations, given the natural background of pathogens, identification of an agent by itself may not be sufficient to conclude whether or not a biological weapon has been used, and the role of off-site laboratories involved in the analysis of samples collected by a SGM Mission may extend beyond the role that OPCW

Designated Laboratories play in chemical investigations.

53 participants from 15 countries (Australia, China, Denmark, Finland, France, Germany, Norway, Portugal, the Russian Federation, Singapore, Spain, Sweden, Switzerland, the United Kingdom of Great Britain and Northern Ireland, and the United States of America), the UNODA, the OPCW, the BWC Implementation Support Unit (ISU) and the World Health Organisation (WHO) attended the workshop. The following report summarises the main findings of the workshop and sets out what workshop participants considered to be desirable next steps towards a network of SGM Designated Laboratories in the field of investigating allegations of the use of biological weapons.

2. Unambiguous Identification – Laboratory Perspectives

The unambiguous identification of the causative agent of a biological incident (whether natural disease outbreak or manmade agent release) is a critical part of any biological SGM investigation. The laboratory data will help to understand and interpret epidemiological, clinical and other findings of the Mission and thus contribute to an assessment of the nature and origin of a biological event. Such a multifaceted interpretation of data is essential – experience has shown that investigations of alleged uses of CBT weapons, as well as of natural disease outbreaks, must cope with a multitude of uncertainties. These can be caused by access limitations in space and time or with regard to the ability to interview and examine victims and eye witnesses, or as a result of the passage of time. As a consequence, this may lead to conclusions that are based on incomplete data sets. The correct interpretation of all data collected by a SGM Mission in context and a clear narrative that explains what can be concluded from the evidence gathered (or not) to a non-technical, political audience is critical for Mission success. Unambiguous identification of the causative agent therefore, is an important aspect of any such investigation.

In general terms, the identification of a causative biological agent involves the demonstration of the presence of a pathogen – including through cultivation, if practicable – then through the identification of genus, species and subspecies of that pathogen, and the more detailed characterisation of the causative agent including signs of atypical or suspect modification (genetic modifications, unusual constituents of environmental samples and the like), as well as kinship to other isolates of known provenance. In case of toxins, it means the assignment of an agent to a (defined) structure and biological activity.

The workshop identified six sets of requirements for unambiguous identification:

- A well-documented and unbroken chain of custody, to be maintained from the sample acquisition all the way through to the reporting of laboratory results;
- Multiple, orthogonal analytical techniques that build up confidence in the interpretation of the results (such a battery of methods may include classical methods such as cultivation, electron microscopy, immunoassays, genetic assays, mass spectrometry and other methods that allow agent fingerprinting; for toxins this may involve immunoassays, genetic assays, mass spectrometry and other instrumental techniques that allow fingerprinting);
- To ensure the required standard of general quality assurance, accreditation to internationally accepted standards (depending on the role of the laboratory, this could for example be accreditation to ISO 17025 for testing/calibration laboratories or ILAC G19 for forensic laboratories) and implementation of relevant codes of conduct (for example for forensic laboratories); if laboratories were to conduct analyses outside their scope of accreditation, there would be a need for demonstrating that and how methods and reference standards/materials had been validated;
- Agreed acceptance criteria for the identification of causative agents (these are still lacking in the biological field);
- Measures to ensure the highest standard of biological safety, and
- The use of methods that may allow differentiating between natural events and manmade outbreaks.

The last point, of course, is at the heart of a SGM investigation and sets it apart from any other outbreak investigation. It will require the combination of laboratory results, contextual information, clinical findings and epidemiological data. The laboratory analysis must include a wide range of methods from genome sequencing all the way to cultivating and characterising the agent and demonstrating its viability, and if possible drawing conclusions about its nature and provenance.

At the same time, samples collected by a SGM Mission have forensic value beyond their content and the characteristics of the agent they may contain. Such forensic evidence may become crucial for establishing the provenance of a sample, in particular if attempts towards attribution were to be made. However, experience has shown that a forensic approach is not something that could be 'retrofitted' – it would need to be in place from the very beginning of the acquisition of evidence, including collection of a sample under the application of chain of custody procedures. This will have an impact on how biological samples should be taken, handled and preserved. Field teams need to be aware of these additional requirements, and so must off-site laboratories (which typically are well versed in biological analysis but may lack the understanding of how to preserve forensic evidence). Guidelines, training as well as awareness raising are needed to ensure that forensic evidence associated with samples gathered and analysed by a SGM Mission is not compromised.

Quality assurance is essential for off-site analysis and identification, and consequently there are high demands with regard to validated methods and reference standards as well as accreditation. Whilst it was suggested that there might be scope for 'flexible scope accreditation', a step short of full accreditation, it became evident that certain forms of accreditation could not be transferred across methods or types of biological agents, and that flexibility was in reality rather limited. Accreditation is usually method-specific, and there was a sense

that gaining accreditation for an unspecified number of methods would be difficult if not altogether impossible. A more practical approach would be to opt for a 'patchwork' of specialised laboratories that over time could share reference materials and standards, and that in their totality would provide an adequate range of methods and capabilities to identify different types of biological agents. To facilitate such an approach, it was suggested that the specific capabilities of laboratories notified by Member States to the SGM should be mapped out to obtain a better understanding of what they were capable of and where specific expertise and capacity was located.

It was noted that accreditation requires considerable up-front investment as well as, perhaps even more important, sustained funding to maintain accreditation status. There was some agreement on the value of standard operating procedures and best practices for sample analyses, however there was also some recognition that a SGM Mission would need to be able to adapt to unforeseen circumstances, and must expect the unexpected.

A central question that emerged during the discussion was whether 'unambiguous identification' is indeed the correct term in case of a biological investigation. Is it even achievable in all circumstances?

The term makes great sense in an investigation of a chemical incident where the suspected agent has no natural background. But in a biological investigation, the more pertinent question is whether one can differentiate between incidents caused by natural causes, accidental agent release, and deliberate use of an agent as a weapon. The ability to identify an anomalous pathogen and determine its likely source of origin is not the same as being able to prove it was deliberately released, let alone who used it. At the same time, the identification of a naturally occurring strain does not necessarily discount the possibility of a deliberate release. Laboratory results, in short, are only one part of the overall aggregate of evidence that a Mission needs to evaluate in order to reach a meaningful conclusion

about whether or not a biological weapon has been used, and what in all likelihood the circumstances of that use have been.

In a biological investigation, instead of using the concept of 'unambiguous identification' it may be more appropriate to think in terms of characterising an agent once identified and interpreting results in the given context, thereby developing a narrative around the results that looked at probabilities, relevance of methods used for identification, and scoring of results depending on the methods used. A SGM investigation (and hence laboratory off-site analyses of samples acquired by such a Mission) is looking for indicators that some of the findings don't fit the context of a natural outbreak, not simply the identification of the agent present.

Nevertheless, it is essential that the causative agent be identified accurately, if there was such an agent. It was pointed out that whilst some methods may be definitive, others would not be so on their own or might no longer be applied given the effect of time (inability to isolate and cultivate an agent in culture). But with a scoring system for methods, it might be possible to combine different methods, which could cumulatively allow a scientifically satisfactory level of confidence in agent identification. This approach was seen as promising and worth considering further, but it would imply a move away from acceptance criteria in the traditional sense, towards a scoring system for acceptable methods of identification.

To develop such an approach will need more work. It is not possible at this stage to identify the standards required or agree on the parameters for such a scoring system. Yet there is room for discussing appropriate scores of different analytical methods to characterise a biological agent for identification purposes, keeping in mind the intricacies of the different agents. Methods that are perfectly suitable for one type of biological agent may not be suitable for another type. Whilst some of the underlying information to develop such a scoring system is available from previous scientific

work including inter-laboratory round robin tests, other data may be missing or is uncertain. Developing such an approach and making it transparent and acceptable to participating laboratories should therefore be part of a wider effort to enhance collaboration between laboratories interested in developing a network of SGM laboratories in the biological field, and eventually moving towards more formalised Proficiency Testing. This must be an iterative process – discussing criteria for the scoring system and testing their utility, refining the scoring parameters, re-testing and eventually agreeing on a scoring system. Only when acceptance criteria and scoring parameters are better defined could formal Proficiency Testing be implemented.

Other issues that were raised during the discussions, and that may deserve further consideration at a later stage, included:

- Whether and how to integrate sample analysis reports provided by accredited laboratories but not acquired with a chain of custody procedure applied;
- Whether, and if so how, a Mission could use analytical results of the diagnostic effort already made as part of an outbreak response, without undermining the credibility of the Mission;
- The impact that different matrices (environmental, clinical, food, etc.) have on sample preparation and subsequent analysis and agent characterisation;
- The value in discussing lists of biological agents – not in order to establish a closed set of 'agents of concern' but to prioritise work, facilitate training and exchanges between laboratories, and to focus efforts towards a common system of inter-laboratory tests.

3. Investigation Mandate

The mandate of a SGM investigation, and consequently that given to a designated laboratory selected for off-site analysis, flows from the Member State request to the Secretary General to conduct an investigation and the instructions which will be set out in the Mission's Terms of Reference.

Such a mandate was perhaps better seen as more akin to a set of instructions and guidelines, an approach that has significant advantages over the more prescriptive approaches usually inferred by the term 'mandate'. Indeed, it was pointed out that instructions from the UN Secretary-General may need to evolve over time and amendments might be required as information emerges from the ongoing investigation and/or from additional input provided by Member States.

Experience has shown that there is a need for flexibility and that tasking, methods and procedures may have to be adapted to the specific context and conditions of an investigation. Adaptations of such kind and deviation from the SGM Guidelines and Procedures are possible in cases where it can be justified with a reasonable explanation or on the basis of sound science.

The purpose of off-site analysis at designated laboratories, firstly, would be to identify the causative agent of an outbreak and, if such an agent can be identified, to characterise it further to obtain clues as to whether the incident allegedly involving a biological weapons attack was in fact the result of a natural disease outbreak, or an accidental release, or a deliberate attack. Laboratory results by themselves will usually not suffice to answer that question, but will need to be interpreted and used in the context of other evidence collected by the SGM Mission team. At the same time, the laboratory results will be an essential part of the totality of evidence available to a Mission to draw its conclusions and answer the investigation questions it was tasked to address.

A further important aspect of the mandate given to designated laboratories is whether tests should be undertaken to extract information from a sample that might allow to establish the provenance of the agent, and (if a biological weapon was indeed used) that may allow to attribute responsibility for that use. Attribution is in principle within the scope of a SGM investigation, provided that the evidence collected and the scientific methods applied to extract and analyse information from the evidence would lead to conclusions that allow such attribution. With regard to laboratory analysis, attribution would pose a number of challenges. Gathering evidence for the purpose of identifying a causative agent was relatively straightforward with the data speaking for itself to some degree. Attribution would require different and additional data sets that allow to establish the origin of an agent identified in a sample (e.g., by linking it to a known and well-characterised source), and even more so to link the agent or delivery system to a particular actor.

Another aspect of the mandate of designated laboratories in a SGM investigation relates to their interaction with the investigators in the field. Previous discussions have highlighted already that, in contrast to investigations of chemical incidents by designated laboratories from the OPCW network (which are kept quite separate from the investigation team in the field), biological laboratories designated to the SGM may need to play a more direct role in the investigative process and may have to become earlier and more closely engaged with the Mission in the field. One reason for this is the absence of a central hub similar to the OPCW Central Laboratory that manages the flows of information and samples from the field investigation to the designated laboratories conducting the off-site analysis. Also, such a central laboratory hub would be important to providing guidance to the Mission in the field about where and how to collect the most promising samples, how

best to optimise its sampling plan, and on sample collection and handling methods most suitable to ensure that subsequent laboratory analysis can achieve the desired results. Furthermore, such a laboratory hub could take on the function of preparing control samples and, based on the direction given by the Head of Mission, preparing technical instructions for those designated laboratories that were selected for off-site analysis with regard to the specific scope of their analyses. Other practical reasons for closer engagement includes overcoming logistical issues related to sample collection, handling and transport, and identifying regulations that may pose a barrier to the transfer of samples to certain designated laboratories of Member States.

However, there are also practical and procedural constraints on an early and direct involvement of laboratories in a SGM Mission: in the early stages of an investigation, it may not be possible to know exactly which types of laboratories may be required for conducting the off-site analysis. At the same time, SGM investigations must remain independent of extraneous influence and bias, and therefore must not be unduly steered by those laboratories that will eventually undertake the off-site analysis. The discussions underscored that a more appropriate approach was to embed laboratory experience with the Mission team. This could be done by incorporating a mobile laboratory into the Mission structure, by assigning expert consultants with the appropriate laboratory expertise to the Mission as points of advice and reference, or even by 'splitting' a designated laboratory into two parts – one directly engaged with the Mission and rendering advice and support, the other one firewalled from that first section and available for off-site analysis.

The discussions also concluded that it would be desirable to undertake real life exercises to build up an understanding of laboratory requirements in biological investigations, and of the most effective and appropriate ways of linking biological laboratory expertise to a Mission in the field. It was

suggested that many of the concerns raised with regard to a closer interaction between the Mission team and designated laboratories in a biological investigation would be resolvable with certain options potentially offering the provision of expertise without creating a bias for the Mission or undermining its independence.

This discussion about the relationship between laboratories and field investigation teams in a biological investigation also included the potential role of mobile laboratories (some of the laboratories nominated by Member States to the SGM are in fact mobile). Mobile laboratories may be useful depending on scenario and context. Experience from the recent Ebola outbreak in West Africa has clearly demonstrated the utility of mobile laboratories for disease diagnosis in-country and support of an outbreak response. Some of the possible support roles that such mobile laboratories could play have already been alluded to above. It would be essential, however, to develop the concepts of a biological investigation in ways that avoid becoming overly dependent on the availability of such mobile units. Their absence could put the entire Mission at risk. There is a need to opt for a more flexible approach that builds on a number of possible options which can be adapted to the specific conditions and circumstances of a given Mission.

It was also important to appreciate the limitations that mobile laboratories face when deployed as part of an investigation: they cannot operate to forensic standards and therefore must not undertake work with regard to authentic samples in the field when it is imperative for a Mission mandate to preserve forensic evidence; they also cannot work to high biosafety standards as they lack a solid floor, and so work procedures will have to be adapted to ensure acceptable levels of biological safety under the given conditions.

A final point raised in the context of discussing the mandate that designated laboratories may receive in a SGM Mission was that it is important to manage the expectations in terms of what the investigation, and as

part thereof the laboratory analyses, can yield. The conclusions of a SGM investigation will be submitted to a political audience, and considered in a political and legal context. Furthermore, SGM investigations are often high profile operations that attract intensive public attention and scrutiny. In either case, it is important that the respective audiences are guided to appreciate the limitation inherent in the investigative and the analytical methods applied. Rather than leading to a binary result (a biological agent was used or not; the agent was of this or that provenance), it was more likely that there would be shades of grey vis-à-vis confidence in specific findings and their meaning for the investigation question. In some circumstances, simple techniques for analysis may suffice to provide adequate and compelling answers to whether or not a biological weapon has been used; however, in other cases, there would be a need to use an array of multiple laboratory methods. Perhaps even more importantly, it is essential that the audiences understand the context within which to interpret the findings of laboratory analyses – thus they should and could not be considered in isolation from other evidence, and neither could the conditions be ignored under which the investigation in the field had been conducted.

4. Reporting of Investigation Results

The report of a SGM Mission on its investigation conduct, findings and conclusions is one of the most critical elements of the investigation. Within this Mission Report, the reports of the designated laboratories of the results of their off-site analysis will play an essential role in substantiating the narrative of the Mission with regard to its findings, and presenting the evidence base for its conclusions.

A credible Mission Report must be sufficiently robust to withstand intensive technical scrutiny whilst at the same time being tailored to the needs of an audience that will assess the conclusions of the Mission in a wider political and legal context. Understanding the audience is critical: it is essentially political but can rely on competent technical advice. Reporting must be technically correct but tuned to expectations, language and culture of the political world, nuanced in conclusions to support political assessments and decisions, and clearly convey the different levels of certainty and uncertainty of the technical findings presented in support of the Mission's conclusions.

It was noted in this context that legal advice could be extremely useful in the construction and sculpturing of parts of a report, but particularly in the articulation of degrees of confidence in the results and conclusions drawn. It was suggested there could also be a role here for expert consultants rendering advice. It was of course understood that any such advice had to remain just that – advice. The content of the report and its conclusions must firmly remain the responsibility of the Mission, and must not be tainted or altered by extraneous advice.

There are a number of possible models for how appropriate reporting can be achieved, including examples from the OPCW, the CTBTO and the SGM Mission in Syria in 2013. The latter is generally seen as a report that was well crafted to respond effectively to the different requirements and expectations pertaining to a SGM Mission Report. It

has shown the value of a short technical summary, combined with presenting sufficient detail regarding the methods, standards and equipment used in off-site analysis (as well as the condition of the equipment), in Annexes of the Report, to allow expert scrutiny of the validity of the analytical results.

An issue that needs to be further considered is how to best strike a balance between preparing a laboratory report that is understandable to a lay audience and manageable in size while providing sufficient technical detail. For a laboratory to demonstrate that it used appropriate analytical techniques and standards that yield validated and reliable results, its report must include methods, validation procedures, quality assurance measures as well as reference materials and standards. Experiences in other areas range from reporting *all* technical details of the analyses conducted to much more restricted reporting backed up by the possibility of submission of additional technical data if so required. The first approach is more akin to scientific publications that would allow other laboratories to replicate the analyses. But it would involve the reporting of vast amounts of technical data including raw analytical data – something that can be managed in electronic format but would not be suitable for a printed report to be presented to a wider audience. The alternative approach would include merely the reporting of the standard operating procedures, materials and methods used and the results recorded, but this approach might not be sufficiently detailed for expert advisers of Member States and other technical audiences to understand and accept the findings and may thus require laboratories to be prepared to submit additional technical detail if so requested.

How this balance is best achieved will in part depend on whether and how the SGM Designated Laboratories have demonstrated their scientific competence, reliability and quality assurance through participation in

collaborative inter-laboratory exercises and eventually Proficiency Tests which use commonly agreed standards and evaluation criteria. Thus creating transparency and confidence among the designated laboratories and for the international community at large.

With regard to the content of the laboratory reporting, it was noted that this was not merely related to identification and characterisation of the agent concerned, but should also include reporting of unusual or unexpected findings in a sample. Such findings can yield leads about the origin of biological agents found in environmental samples, for example with regard to a geographical imprint related to raw materials used or a discrimination of organic compounds of biological or petrochemical origin (for example using stable isotope abundances). Other examples mentioned in the discussion included the detection of DNA fragments indicative of growth media used, or the use of data mining techniques to fingerprint

samples to their possible geographical origin.

Such analysis may require laboratories to undertake work outside their scope of accreditation, which in itself was not considered problematic as long as care was taken to validate the methods used – and that validation must of course form part of the technical reporting on the results of the off-site analysis conducted.

Finally, there was a discussion around the speed of reporting. Many audiences likely want results to be reported quickly, but there was a need for caution in providing a quick preliminary response. Such preliminary responses carry the risk of inconsistencies with subsequent detailed findings during the completion of the laboratory work and the evaluation of all evidence collected by the Mission, leading to confusion and potentially undermining the confidence in the Mission's conclusions.

5. Consolidation – Progress and Achievements

There is under way today a broadly supported process of assessing what needs to be done to enhance the operational capacity of the SGM, in particular with regard to investigations of alleged uses of biological weapons. Several workshops and lessons-learned exercises have helped clarify requirements for enhancing the SGM operational capacity, including the developing of a more strategic training concept for experts nominated to the SGM roster, and by clarifying the role of designated laboratories and taking steps towards the formation of a network of such laboratories.

These discussions have underscored the importance of such factors as quality assurance, robust scientific basis for an investigation, adaptability and flexibility of methods and procedures, the importance of multi-tasking and soft skills such as interviewing techniques or command and control functions of a Mission, the demands for effective data management to support evidence gathering and evaluation, and the need for effective team management to ensure Mission coherence.

These discussions have underscored that the role of the laboratories in biological investigations in certain respects may be different from chemical investigations, and that laboratory guidance and advice ought to get involved at a fairly early stage of an investigation – notwithstanding the need to maintain independence of the laboratories that conduct the off-site analyses. There will nevertheless be a need for laboratories to provide advice to a Mission on sampling strategy and methodology. Options for how laboratory expertise can be embedded into a SGM Mission have been identified. Furthermore, these discussions have recognised the desirability of technical guidelines for investigation teams regarding sampling in the field. The gold standard in analysis remains isolation and cultivation of the pathogen. Consequently, sampling and sample handling and transport to the extent possible have to be performed in a timely

fashion and in ways that can keep a biological agent alive. There is a need for training – not only in techniques and concepts but also covering the interaction between laboratories and the Mission team, presentation of findings and conclusions in laboratory reports as well as Final Mission Reports.

Discussions so far, as well as experience from practical exercises, have shown that mobile laboratories could play a valuable role in the triage and transfer of samples, or in directing the sampling process. Moreover, they could serve as support platforms for the Mission. It was argued also that Member States that wished to contribute through the provision of such mobile units should not be precluded from contributing in this way. However, it was indicated that exactly how such units currently fit into a SGM Mission remains to be further clarified, as there are both operational challenges and political sensitivities. It was suggested that there is perhaps a need to caution against rushing to integrate such units and focusing too much attention on mobile laboratories as this also could set a Mission up for failure (creating single points of Mission criticality). Nevertheless the role of mobile laboratories and the interface between them and the Mission team should be further studied and developed.

A critical issue is the current lack of detailed knowledge of the capabilities and capacity of the laboratories nominated to the SGM. At this point in time, it would be difficult to see how the UN Secretary-General could elect the relevant laboratories for off-site analysis (as well as Mission support) in the absence of a transparent and demonstrated capability portfolio of the laboratories nominated by Member States. This deficit could of course be addressed through *ad hoc* negotiations and information exchanges as a Mission unfolds, but that is less than satisfactory for an effective investigative mechanism that could be called upon on short notice. There is a need for objective

criteria in the selection of laboratories to ensure competence, something – it was suggested – was particularly important for biological off-site analysis given the absence of calibration studies in the past.

6. Towards a SGM Network of off-site Biological Laboratories


This second SGM Workshop held in Spiez has underscored that there is considerable interest as well as broad support among the participating laboratories and countries in moving towards practical steps to enhance the operational capacity of the SGM and to move a step closer to establishing a network of off-site laboratories designated to the SGM. This will be an incremental process – it will also require engagement with a wider range of relevant laboratories that may be part of existing networks, including the networks of WHO and OIE, and a gradual step-by-step approach.

There was strong support for the following next steps to be considered:

- Moving towards a more systematic approach to Member States nominations of laboratories, experts and expert consultants based on an analysis of the operational needs of the SGM and the current capabilities and capacity available to UNODA;
- Development of a matrix of current competences and capacities of laboratories nominated by Member States to the SGM (a capability and gap analysis), which could be accomplished, *inter alia*, by an analysis within UNODA of the nominations on file, by table-top exercises and by circulating a questionnaire to laboratories nominated to the SGM Roster;
- Conducting simple inter-laboratory tests to gain experience with regard to SGM requirements and to build confidence among the laboratories, taking into account also the need to ensure sustainability of such a network and securing the long-term commitment of the laboratories as well as their countries;
- Development of a set of identification criteria and a scoring system for different methods used in agent identification. This could be tested and reviewed in an iterative process of discussions and practical tests, thereby gaining confidence in the approach;
- Practice the writing of SGM reports and expose laboratories to this process and the specific context and demands of a SGM investigation. This could for example be done using data from real life cases;
- Engaging with the heads of laboratories nominated to the SGM to begin a two-way conversation with them on issues such as sampling and analysis for SGM investigations of biological incidents;
- Identification of a manageable number of representative agents (bacterial, viral, toxins) for the purposes of training and inter-laboratory tests; these agents could also form the starting point for the development of identification criteria and the proposed scoring system for methods required to identify a biological agent;

In preparation for the next workshop in June 2017 organised by Switzerland, practical steps must be initiated. These include developing a scoring system for laboratory methods and criteria for reporting the results of such methods, both to be tested in a table-top study. In parallel, preparations must commence by parties willing to contribute for an inter-laboratory testing project to build confidence among laboratories.



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