Transparency visit to the Lugar Center, Georgia: An Independent Report

SUBMITTED BY GEORGIA

- Georgia reported on its peer review transparency visit to the Richard Lugar Center for Public Health Research (Lugar Center) of the National Center for Disease Control and Public Health (NCDC) in Tbilisi in working paper BWC/MSP/2018/WP.5.
- 2. This working paper provides an independent report by Dr Filippa Lentzos of King's College London, and should be viewed as supplementary to BWC/MSP/2018/WP.5.
- 3. The working paper provides substantial background on the Lugar Center; details the preparation for, and activities of, the two-day site visit; describes the visiting team's report on the visit; provides reflections from the author; and outlines the presentation and discussion of the transparency visit at the BTWC meeting of states parties.

Introduction

In a 25 July 2018 letter to BTWC states parties, the Georgian Ministry of Foreign Affairs invited all interested BTWC states parties to a transparency visit to the Richard Lugar Center for Public Health Research (Lugar Center) of the National Center for Disease Control and Public Health (NCDC) in Tbilisi, Georgia. The invitation was publicly communicated through a working paper to the August meeting of experts on strengthening national implementation.¹

Planned for 14-15 November 2018, the primary objective of the visit, as outlined in the invitation, was to demonstrate that the Lugar Center complies with the provisions and obligations of the BTWC. Through the transparency exercise, Georgia aimed to show that such on-site visits can enhance confidence in compliance with the BTWC. While it was recognised that such on-site visits only represent one of many ways in which confidence in compliance can be strengthened, it was emphasised that they are particularly useful for connecting discussions on implementation with concrete every-day procedures on BTWC-relevant sites. It was also emphasized that transparency visits are not a substitute

¹ BWC/MSP/2018/MX.3/WP.2

for verification nor comparable with a compliance mechanism. In other words, the objective was not for the visiting team to make a formal judgement about whether Georgia and the Lugar Center are in compliance or not, but, instead, the aim was to provide the team with <u>increased confidence</u> that Georgia and the Lugar Center are in compliance. The visiting team was to record its findings in a concluding summary, that would be made open to all BTWC states parties.

Building on similar visits in Germany in 2016 and in Morocco in 2017, the visit was also intended to demonstrate that it is possible to reconcile a high level of transparency with the legitimate security and intellectual property interests of the visited facility. It was hoped that the visit would encourage other state parties to conduct similar exercises in future.

The organisation and implementation of the exercise was supported by the German Federal Foreign Office, which would provide financial support for travel and accommodation on request. For capacity reasons, a maximum of 20 visitors would be accommodated, and, to ensure equal representation, the places would be filled with participants from all regional groups.

The author was invited as a civil society representative to act as a participant with an independent view. This report details her observations of the experience. It gives background on the Lugar Center; details the preparation for, and activities of, the two-day site visit; outlines the visiting team's report on the visit; provides some reflections from the author; and describes the presentation of the transparency visit to the BTWC meeting of states parties.

Background

The Lugar Center is a public health research facility declared under the Confidence-Building Measures (CBMs) submitted by Georgia. Named after US Senator Richard Lugar, who initiated the renovation of lab networks in former Soviet states, the Lugar Center became operational in 2013. It has the first high-containment laboratory in the region that meets Biosafety Level (BSL) 3 standards, meaning it is equipped to study serious or lethal human diseases including BTWC-relevant pathogens. It is a civilian facility, and its missions and main functions are to:

- provide Georgia and the wider region with detection and diagnostic capacity for disease outbreaks
- provide lab support to public health programs in Georgia
- provide zoo-entomological surveillance
- develop biomedical research potential in Georgia

- consolidate Especially Dangerous Pathogens (EDPs) in a secure place
- lead facility responsible for biological safety and security
- provision of lab-based surveillance in compliance with the WHO's International Health Regulations (IHR)
- participation in the Global Health Security Agenda

The United States Walter Reed Army Institute of Research (WRAIR) is a tenant unit of the Lugar Center, and a small number of American military personnel (9) work at the facility.

The transparency visit to the Lugar Center took place against the backdrop of a series of increasingly confrontational statements in which Russia questions the purposes of the United States Department of Defense presence at public health laboratories in former Soviet states, and in particular at the Lugar Center in Georgia.²

Pre-visit briefing on the 'facility provisions'

On the day before the visit, at a short pre-visit briefing in the afternoon of 13 November, the experts and observers of the visiting team met as a group for the first time. Both the hosts and visiting team members introduced themselves.

The visiting team comprised national experts and diplomats put forward by states who had applied to participate. In their invitation to states parties, the Georgian Ministry of Foreign Affairs had noted that it particularly welcomed experts from the fields of biology and virology, as well as infectious disease specialists. All participants had to be willing to comply with the appropriate safety regulations for entering biological laboratories. A maximum of four bioexperts would be able to access the high containment BSL-3 lab suite. These experts would be required to present a certificate confirming their prior experience of working in a BSL-3 laboratory and fulfil specific health requirements. A total of 19 state representatives participated in the visit, from: Austria, Bosnia and Herzegovina, Cameroon, Chile, Colombia, Germany, Hungary, Iraq, Italy, Kazakhstan, Malaysia, Mali, Montenegro, Myanmar, Uganda, United Kingdom, and the United States of America. In addition to states parties representatives, three representatives from the European External Action Service, the BTWC Implementation Support Unit (ISU) and King's College London participated.

² https://thebulletin.org/2018/11/the-russian-disinformation-attack-that-poses-a-biological-danger/

At the pre-briefing, the visiting team was given a document pack on 'facility provisions.' The documents provided information relating to various aspects of the visit. These included:

- (1) **The principal objectives of the visit** (summarised in the 'Introduction' section of this paper).
- (2) Extracts from the 2016 Confidence Building Measures (CBM) Form A, part 2(iii), which provided details on the name, location, lab floor areas by containment level, personnel, scientific disciplines represented in the staff, contractors, funding levels and sources, and the facility publication policy. Additionally, overview diagrams of the NCDC and Lugar Center organisational structures were provided. Also included were a photograph of the Lugar Center from the outside, and two Google Map satellite images of the NCDC at its Mikheil Asatiani Street address in Tbilisi and of the Lugar Center and the new NCDC administrative building on the site.
- (3) A briefing on the general health and safety provisions of the Lugar Center to be observed by external personnel, including the visiting team. No filming or photographing was permitted, and visitors were not to operate lab equipment or use the lab IT. The sub-team of four visitors who would enter the BSL-3 lab was required to adhere to additional health and safety provisions, including requirements to wear the personal protective equipment provided and to shower as part of the lab exit procedure. Conduct in case of an accident was also outlined in the provisions.

The Lugar Center is a restricted area and the visiting team was to be escorted at all times (e.g. visibly wearing name badges and following escort personnel instructions). In advance of the visit, visiting team members had been requested to complete a 'visitor access request' form, providing details of their names, dates of birth, passport numbers, contact details, and the purpose and duration of their visit.

(4) **The administrative and operational procedures for the visit**. These procedures related to the notification of visitors (completion of the 'visitor access request' form), the size of the visiting team (limited to 20 overall, and 4 for the BSL-3 lab), the selection of a visiting team leader, the duration of the visit (max two days, to be conducted during regular working hours), the requirement to wear protective and safety equipment in the BSL-3 lab, restrictions on the use of IT and communication equipment, and the visit briefing (see the following

'Briefing' section of this paper). The working language of the visit would be English. A proposed schedule for the visit was appended.

(5) **Provisions governing the conduct of the visit**. The escort team and the facility staff were to "strive toward demonstrating the highest level of transparency and openness in all BTWC-related matters." They were to "endeavour to discuss any ambiguities as soon as possible and in a cooperative manner."

The visiting team was only to collect "such information as is required to establish openness and transparency in accordance with the BTWC." The findings gained during the visit were to be treated as confidential, and not released to the public.

Few restrictions were placed on the visiting team other than those related to safety and security. The team was free to view rooms, lab equipment and installations. It was noted that due to national security aspects, biosafety and health regulations, data privacy issues, not yet published scientific results, or ongoing lab work, there may be individual cases where access may be granted to a limited extent or not at all. In such cases, the visiting team would be provided with explanations, and alternatives offered. The type and scope of access was to be determined by facility staff on a case-by-case basis.

The team was allowed to request visual access to paper documents. The team could speak with facility staff and interview personnel more formally; it could also submit written questions, which would then receive written answers. While the team was not allowed to bring its own cameras, it could request photographs to be taken by the escort team. The photographs would remain with the hosts, but an index of the photographs taken could be attached to the visitors' summary. GPS would be available if the team wished to determine or confirm any geographic coordinates.

(6) **The visit findings**. As had been noted in the invitation to the visit, the visiting team was expected to produce a factual summary of the visit, to be prepared on site. The summary was to be agreed by consensus. In cases of divergent views within the team, these were to be included in the summary so that all opinions were reflected. The escort team and facility staff were to cooperate with the visiting team in producing the summary by providing and explaining relevant information on request.

In a final discussion, the summary was to be presented to the escort team and facility staff, who was to be permitted to make comments or suggested amendments to ensure the summary is factually and technically sound, and to protect information related to national interests as well as to personal proprietary rights. Distribution of the summary would be the responsibility of Georgia.

At the pre-briefing, all visiting team members had to sign forms to acknowledge that they had received the health and safety briefing. Also at the pre-briefing, the team leader and the sub-team of four visitors who would enter the BSL-3 lab were self-selected, and approved by silent consensus.

A general outline of the visit programme was as follows: A briefing on the morning of day one. In the afternoon, the visitors would tour the Lugar Center facility and BSL-2 labs, and interact with staff. During the morning of day two, the sub-group of four visitors would visit the BSL-3 lab complex, while the rest of the visitor team would tour the site premises including the administrative building, warehouses, incinerator, generators and water tanks. In the afternoon, the visiting team would have time to discuss their assessment of the visit and prepare their summary report, before presenting it to the hosts in a concluding plenary.

Briefing

The visiting team was bussed to the NCDC site on the morning of 14 November, arriving around 09:30. The team was brought to a large meeting room on the ground floor of the administrative building. There were no security checks, and phones and laptops could be brought into the room.

In an effort to be as transparent as possible, the hosts had decided to make the initial part of the briefing open to the press with no requirements to register in advance. While the visiting team had been made aware that there might be some media present, the extent of the presence took most of the visiting team by surprise. There had been no, or very limited, media presence at previous peer reviews. The team was filmed stepping off the bus, entering the meeting room, and during the briefing in the meeting room. There were 4-5 video cameras, 4-5 microphones, several photo cameras, and more than a dozen members of the press. The media was primarily Georgian, with at least one Russian TV channel present.

While the visiting team waited in the meeting room for the 10:00 o'clock start, the media interviewed the Minister of Health of Georgia and the Deputy Minister of Foreign Affairs of Georgia outside the room. The author was asked to provide an impromptu press conference, which she accepted. She was asked two questions: what was the purpose of the visit, and whether she was aware of

the Russian allegations. Other members of the visiting team had also been asked if they would be willing to speak to the press, but they declined, having had such limited advance warning and therefore no agreement from capital to do so.

The Director General of the NCDC, Amiran Gamkrelidze, opened the meeting and gave some short welcoming remarks. There were around 45-50 people in the room, consisting of the hosts, NCDC staff, the visiting team and members of the press. The Director General then introduced the Minister of Health of Georgia and the Deputy Minister of Foreign Affairs of Georgia. The Minister of Health gave a short welcoming address, listing the countries represented by the visiting team. The Deputy Minister of Foreign Affairs focused her remarks on the objectives of the visit, emphasising how the visit demonstrates that the Lugar Center is an open institution which complies with the obligations of the BTWC and meets international standards of biosafety and biosecurity. The remarks appeared primarily aimed at the media presence in the room, and were highly political, with the Deputy Minister of Foreign Affairs characterising the visit as a "tool to counter false media propaganda."

The visiting team was asked if they had any questions. Nobody raised any; many government representatives being unable to do so with the media present. To round off the formal, public part of the programme, group photographs were taken by NCDC staff as well as the media.

Following this, the visitor team were led out of the building and across to the security check point of the fenced off Lugar Center. In a stand-alone security building, visiting team members left any laptops in secure storage provided, and collected their site badges in exchange for their passports and phones. One member of the team had forgotten his passport, and other forms of ID such as a national driver license were not considered sufficient. He was driven back to the hotel to retrieve his passport, and he re-joined the group about an hour later.

Similar to airport security, all visitors walked through a security scanner and bags went through separate security scanners. The team was led into a meeting room on the ground floor of the Lugar Center for the second, more technical part of the briefing. Lugar Center staff was also present, including WRAIR personnel, who were ready to answer any relevant questions should any be posed.

The Deputy Director General in Science of NCDC, Dr Paata Imnadze, delivered a presentation on the Lugar Center's capacities, current activities and BTWC implementation. Copies of the presentation slides were provided in both electronic and hardcopy to the visiting team. The presentation provided a brief introduction to the NCDC covering its history, organisational structure, mission, lab network, public health programmes, and surveillance of infectious and non-communicable diseases. Budget data, from 2017, was also provided broken down into public health programmes, global fund programmes, grant projects, central budget, and commercial activities.

The main portion of the presentation comprised an extensive introduction to the Lugar Center. The presentation outlined the Center's mission and main functions, and it gave an overview of the Center's two main departments. The Department of Biosafety and Especially Dangerous Pathogens (EDPs) contains the biosafety division, the national repository, the EDP lab, the zoo-entomology lab, the general bacteriology lab, the vivarium and the sample reception. The Department of Virology, Molecular Biology and Genomics contains the molecular epidemiology lab/genomics, the influenza and respiratory viruses lab, the polio and other entero-viruses lab, the cell culture lab, and the serology lab.

The presentation provided figures on the lab and human capacity at the Center. The BSL-2 and BSL-3 lab floor area were consistent with that listed in the 2016 CBM. It was explained that the Center was originally built to provide greater BSL-3 capacities than what is currently in use. Some of the originally intended BSL-3 space did not pass certification and would need additional reconstruction to be operational as a BSL-3 lab; it is currently used for serology and field material preparation. The remainder of the additional, originally intended BSL-3 space is currently used at a lower (BSL-2) containment level for general bacteriology, rotavirus serology, field material DNA/RNA extraction, PCR rooms for polio and influenza labs. The presentation made clear that the Center did not anticipate a need to start using the unused potential BSL-3 space in the forseeable future.

The staff figures at the Center were updated from those listed in the 2016 CBM. Staff numbers were also provided for outsourced services: facility engineering and technical support, and facility physical security. Funding figures were also provided, broken down into five categories (security service, laboratory supply, operational costs, salaries, project funds) and the distribution of the funds across research, development and tests/evaluation.

Lab accreditations and certifications were provided. The Lugar Center has three labs accredited by the WHO (on polio, influenza and measles/rubella), and five labs connected to the WHO lab network with external quality assurance (rota, invasive meningitis, malaria, salmonellosis, AMR). The Center is also ISO15189 and ISO 9001 accredited. The Lugar Center acts as the national repository of bacteria and viruses. The presentation described how data on pathogens are registered, monitored and accounted for – both in logs and in an electronic pathogen asset control system (PACS). The presentation also provided information on the frequencies of the inventories and audits conducted of the strain collection, and provided dates of the most recent ones. Numbers of strains held of key EDPs were also provided.

Details about samples analysed at the Center in 2017 were listed. In terms of EDPs, for example, this included 1030 soil samples, 878 ectoparasite samples, 1365 rodent samples, 5 food product samples, and 145 clinical samples. Only 18 of these were confirmed EDP cultures.

Presentations were provided of on-going projects at the Lugar Center. These included projects: to characterise up to 100 selected pathogen strains from the Georgian NCDC strain archive to provide a greater understanding of their genetic variability and functional capabilities; to characterise Yersinia strains in rodent populations to gain greater insight into the molecular epidemiology and ecology of the transboundary plague endemic territory in Georgia and Azerbaijan; and to characterise the regional bat coronavirus to gain greater understanding of the risk of bat-borne zoonotic disease emergence in Western Asia. 'First time' scientific achievements, both in the world and in Georgia, from research at the Lugar Center were also listed. This included the 2013 discovery of a new species of Orthopox virus, now named the Akhmeta virus after the Akhmeta region in Georgia where the virus was first identified (published in the *New England Journal of Medicine*), Brucellosis pathogens identified in bats, and cowpox detected for the first time in Georgia in 2016 in the Abasha region.

Select publications were listed, and included articles in reputable, peer reviewed, foreign journals like *PLOS/ONE*, the American Society for Microbiology's *Genome Announcements*, the *Journal of Global Antimicrobial Resistance*, and the *Journal of Bacteriology and Mycology*.

International partners and projects were also listed, and included a range of American and European institutions, as well as international organisations like the WHO, OIE and UNICEF. Georgia's contributions to Global Health Security Agenda (GHSA) action packages were also highlighted.

The Lugar Center's outreach through workshops and international training provision, including for biosafety and biosecurity, were mentioned. As were the Center's efforts to train the next generation. These include doctoral training abroad, for instance at German partner institutions as part of the project to establish a Western Asian network for the improvement of biosecurity in the Caucasus region, and internships at the Lugar Center for local university students and research contributions to Bachelor and Masters thesis.

Dr Imnadze's presentation lasted approximately an hour. Several questions were posed to the briefing personnel, and were answered satisfactorily, either by Dr Imnadze, or by other Lugar Center staff, as appropriate.

Hardcopies of recently published supplementary material was also provided, including an introductory pamphlet to the NCDC providing a brief overview of its mandate and structure, strategic priorities and main areas of activity, the Lugar Center, international collaborations, global fund programmes for HIV/AIDS and tuberculosis, and the GHSA; NCDC key achievements and challenges 2012-2017; and the NCDC Strategic Plan 2018-2022. These publications were all in English.

The facility and site premises tours

In the afternoon of 14 November, the visitor team was shown around the Lugar Center. The team was split into two groups, both completing the same tour. The groups were pre-arranged, to ensure a mix of expertise in the two groups, but visitors were free to switch groups should they prefer.

The teams, escorted by four/five hosts, visually examined lab equipment and installations in all BSL-2 laboratories. In most of the labs, short presentations were made to the group to explain the work of the particular lab. The presentations tended to be followed by several questions from the visitor team. Throughout the tour there were opportunities for one-on-one conversations with the scientific and technical staff and with the escort staff. There were often multiple conversations going on simultaneously.

The BSL-3 lab suite could also be viewed from the outside from multiple angles through windows. The autoclaves and entrances to the airlocks could also be readily observed from the outside. Three people were at work in the BSL-3 lab, two of which were from the Ministry of Agriculture.

In addition to the laboratory space, the team was shown the sample reception and the route by which samples are brought in to the sample reception and then passed on to the appropriate laboratories in the facility for analysis. The team was shown the vivarium designed for animal work, but which is not used as such; and the team was shown storage and administrative areas, the mechanical room with power generators, ventilation and heating system, the boiler room, the operations room, the central security room, and the laundry. The team was also taken up onto the roof. The team was provided with visual access to paper documents and electronic records on request. The author observed at least half a dozen such requests. The sorts of documentation visitor team members asked for included Standard Operating Procedures (SOPs), material safety data sheets, registration forms for samples and samples rejection forms, relevant legal documents (on e.g. export controls, biosafety, patient's rights), risk assessment manuals, biosafety committee minutes, and documentation on biosecurity and biosafety training. Some of this material was provided in Georgian.

As part of the tour, the team was also given access to the WRAIR lab and its staff. In the WRAIR lab, a presentation was provided to the group about ongoing research projects, and included projects with objectives to:

- Characterize causes of undifferentiated acute febrile illnesses in Georgia and other South Caucasus countries.
- Collect and analyse bacterial isolates recovered from clinical samples (blood and urine) of suspected HAIs; detect identity as well as antimicrobial resistant patterns, monitor current and emerging resistance; and, provide SME support to the host nation.
- Conduct new advanced Tac Array card test to simultaneously detect multiple different enteric pathogens in stool samples and screen collection of stored acute diarrheal stool samples.
- Determine the prevalence of norovirus (NoV) and Enterotoxigenic Escherichia coli (ETEC) in US populations in Georgia, and determine antimicrobial resistance of ETEC isolates.
- Study the causes of acute respiratory infections (ARI) in Georgian personnel. Pathogens of special interest, particularly influenza and adenovirus, may undergo full-length genomic sequencing to better understand pathogen epidemiology, the clinical spectrum of infections, or the potential to identify influenza vaccine strains.
- Determine the prevalence of selected sexually transmitted infections in Georgian personnel.
- Identify accurate and practical biologic tools to estimate HIV incidence in Georgia so that HIV prevention and treatment programme can appropriately utilised.
- Identify accurate and practical biologic tools to estimate HIV incidence of newly diagnosed HIV 1/2/ cases in Georgia.
- To identify mosquitoes (including invasive mosquitoes), sand flies and ticks present in Georgia and determine their distribution.

Hardcopies of the presentation slides were provided to the visitor group, which contained the disclaimer that there is no objection to their presentation and/or publication. The WRAIR work at the Lugar Center has an open publication

policy and there is no classified work undertaken. Specific lab equipment was also presented to the group in the WRAIR lab, and group members could walk freely around the lab. Group members asked informal questions to the scientific and technical staff, both in the group and one-on-one. These were answered satisfactorily.

Before breaking for the day, the two groups reunited in the meeting room. The entire visiting team had a short debrief with the hosts where further questions were asked and answered. Several documents were also requested, and these would be provided the following day. The hosts then left the visiting team to exchange notes and initial impressions among itself, which it did for the remaining 45 minutes until the bus was scheduled to depart.

On the morning of 15 November, the sub-group of four visitors entered the BSL-3 lab. The sub-group accessed all areas of the BSL-3 lab. It spent three hours with the escorts observing and discussing the Pathogen Asset Control System (PACS), the sorts of BSL-3 lab projects conducted, the biosafety, biosecurity and general oversight systems that was in place, the procedures for pathogen and toxin control and transfer, and so on.

The rest of the visiting team examined the facility's premises and surrounding buildings. The visiting team was shown the incinerator and incinerated waste storage, fuel reservoir tanks, boiler and generators, water system and water tanks, perimeter security and security towers, diesel pumping station, container storage units, warehouses, vaccine storage facility, and the entire administrative building from roof to basement including the suite of half a dozen offices occupied by WRAIR staff. All doors were open to the team.

Everywhere, specialized staff (including scientists and technicians, but also engineers, maintenance staff, security staff, warehouse staff, administrative staff) was on hand to give the visiting team short introductory presentations and to answer questions. On occasion, the presentations or Q&A went through translators. The host staff often asked for feedback from the visiting team on how practices or procedures can be improved.

On completion of the facility and site premises tours, the visiting team was confident that access had been provided to all areas of the facility and site.

The visiting team's report

In the afternoon of 15 November, the visiting team drafted its summary report. The team was provided with a conference room in the NCDC administrative building for the purposes. No hosts were present and the doors were closed. In advance of the drafting session, NCDC and Lugar Center staff had made various documents available that visiting team members had asked for during the tours of the facility and premises. These documents were left for perusal in the conference room during the drafting session.

The team leader had helpfully prepared an initial draft so that the group did not start on a blank page. Team members were invited to make comments and suggest additions and amendments, which they did. There were no real divergent views within the team, only difference in emphasis and wording. Still, because of the political context in which the team knew the report would be used, it took nearly three hours to finalise the report.

The escort team and facility staff were on standby during the drafting session, should the team require further, or clarifying, information. No further input was required by the team; only administrative support to print an early version of the summary report.

The final summary report was a short document of 11 paragraphs. The visiting team deemed the size of the laboratory areas, number of personnel, scientific disciplines represented in the scientific/engineering staff, and information on types of pathogens and toxins handled and studied in the facility to be consistent with the information provided in the CBMs and other information provided to the visiting team.

The team noted the following:

"Physical security measures included secured perimeter fencing, surveillance and monitoring system, security checks, security guards and several layers of access control (access cards, PIN code, biometrics devices, keys, etc.) to prevent unauthorised access to sensitive areas. Staff and visitors are required to wear identification badges. All visitors are required to complete the Visitor Access Request form at least 72 hours in advance and are escorted on site. All staff, including contractors and cleaning and maintenance staff, must undergo security vetting on a regular basis.

All the equipment and infrastructure observed was relevant to the prophylactic, protective and other peaceful research and diagnostic purposes stated by the visited facility. Several laboratories are accredited to international standards such as those of ISO and WHO. Biosafety and biosecurity measures were demonstrated to meet international standards.

Pathogens handled by the facility are kept in a repository and the process for access control and inventory management, including auditing, was explained in detail to the visiting team. A demonstration of the Pathogen Asset Control System (PACS) was also given to the team. The pathogen strains held are consistent with use for prophylactic, protective, and other peaceful purposes. The Center has trained personnel certified by the International Air Transport Association (IATA) to prepare and ship hazardous materials. Decontamination processes and waste management procedures are in place and were explained in detail.

Documentation was also provided to the team upon request, including national legislation relevant to the implementation of the Biological and Toxin Weapons Convention (BTWC), quality and biosafety manuals, Standard Operating Procedures (SOPs) on emergency response and training, biosafety committee meeting records, maintenance records, staff training records (technical, biosafety, biosecurity, emergency drills, etc.), and agenda and schedules for training on dual-use bioethics, including BTWC obligations.

Staff were made available for interviews and to answer questions throughout the visit. This included maintenance, engineering, security, administration and operational staff, in addition to the relevant scientific and technical experts. Throughout the visit, all laboratory personnel and escorts were very engaged and responsive to questions and requests for access to facility areas, documentation and information. These interactions allowed exchange of best practices on a number of occasions. Laboratory staff indicated a desire to participate in international External Quality Assurance Exercises in the future.

Procedures for biosafety, biosecurity and dual-use research; handling and transport of pathogens and toxins; biosafety and biosecurity education and awareness programs; and other measures mentioned demonstrated commitment to implementing the obligations under Articles III and IV of the BTWC. Information was also provided on regional and international assistance and cooperation activities relevant to Article X of the BTWC."

The visiting team's conclusion was that "the facility demonstrated significant transparency about its activities" and that "the visiting team observed nothing that was inconsistent with prophylactic, protective and other peaceful purposes."

The hosts were invited to join the visiting team in the conference room at 17:50. The summary report was then presented to NCDC and Lugar Center staff, and the visit was formally adjourned following the presentation.

Reflections

The transparency visit demonstrated Georgia and the Lugar Center's implementation of the provisions and obligations of the BTWC, and it increased

states parties' confidence in Georgia and the Lugar Center's compliance with the Convention. As such, the principal objectives of the visit were met.

The visit was carried out in a professional manner. Staff acted professionally, and were open, helpful and informative. There was a clear commitment to implementing biosafety and biosecurity measures and practices of the highest standard.

The visit provides a valuable contribution to states parties' efforts to increase confidence in the implementation of, and compliance with, the BTWC. There were minor issues that could be improved in future. Some of these were logistical. For instance, it would have been beneficial for the visiting team members to meet as a group beforehand, to agree on the team's roles and remit, and to provide more detailed presentations of their backgrounds and the particular expertise they brought to the team. It would also have been useful to be given the facility provisions in advance of the visit so that team members could better prepare. More information in advance on the host country and visited facility's implementation of the BTWC, and on the facility to be visited in general would also be welcome. The impromptu team debrief at the end of the day on November 14 was very helpful as a way to collectively check in with everyone to get an initial sense of others' impressions, and to ask if anyone had wanted to see something but not been shown it or if anyone had any unanswered queries. This sort of debrief could easily be built into a future visit's programme. During the Lugar Center visit, care was taken to minimise personal identification of Lugar Center staff, but not that of visiting team with images and videos of visiting team members publicly shown in media and online. This tension between wishing to be transparent about the visit and personal privacy was probably heightened because of the context of this particular visit, but could be addressed in future through better communication in advance.

Other issues for possible improvement relate to the exchange of information and experiences between peers. During the visit, exchanges of best practices took place between visiting team members and facility staff on a number of occasions. It might be useful to think about ways in which to encourage further exchanges of best practices among peers, such as the introduction of follow-up mechanisms to build on and sustain the initial dialogues and links that were made during the visit.

A final issue concerns perceptions of transparency visits. Some of the 'provisions governing the conduct' of the Lugar Center visit outlined in the 'facility provisions' are more in line with a compliance assessment, an inspection or an investigation, than they are with an invited transparency visit where the objective is to demonstrate national implementation. This relates particularly to the methodology, and specifically to the use of formal interviews,

submission of written questions, requests for photographs, and requests for geographic coordinates. Formalising the visit in this way is unnecessary. In fact, it could be counterproductive, because it could give the impression that the visit is more of a compliance assessment, inspection or investigation. This also extends to the name 'facility provisions' – it could just be called an information pack or something less suggestive of something more intrusive.

Overall, however, the visit was exemplary.

To conclude, this visit was a much more politically sensitive visit than preceding peer reviews. The visiting team felt this during the visit, particularly through the media presence at the start of the visit, but it also shaped the questions that were asked and the things that were looked for.

Peer review is an important way to concretise discussions about trust and transparency in biological disarmament. It is the author's sincere hope that the political nature of this particular visit will not compromise the idea of peer reviews and transparency visits in general. They are useful as a tool to improve and strengthen national implementation, and they can form an important step on the way to more formal compliance assessment.

Presentation of visit to BTWC MSP

The visiting team's report was publicly communicated through a working paper to the December meeting of states parties.³ The working paper was submitted by Georgia and Germany, and co-sponsored by Austria, Belgium, Columbia, Iraq, Hungary, Malaysia, Mali, the United Kingdom and the United States of America.

In addition, the transparency visit was presented and discussed at a public side event to the meeting of states parties. Held on 4 December 2018, the event was chaired by Ambassador Peter Beerwerth, Permanent Representative of Germany to the Conference on Disarmament. Opening remarks were provided by Ambassador Beerwerth, Ambassador Yann Hwang, Permanent Representative of France to the Conference on Disarmament, and Ambassador Victor Dolidze, Permanent Representative of Georgia to the UN Office and other International Organizations in Geneva. An introduction to the transparency visit was provided by Dr Paata Imnadze, and reports were provided by the visiting team leader, Kathryn Tham Bee Lin of the Ministry of Defence Malaysia, and by Dr Filippa Lentzos, King's College London. Dr Emil

³ BWC/MSP/2018/WP.5

Kazakov from the European External Action provided an outlook on EU support to the BTWC, in particular voluntary peer review exercises.

Following the presentation, comments were made by Russia, China, the United States, the United Kingdom and Sweden. Some of the key points made related to:

- divergent views on the purposes of transparency visits
- the lack of a robust methodology for transparency visits in general, leading to the potential for politically motivated conclusions to transparency visits
- the usefulness, or not, of sampling and analysis for this type of visit
- potential methodological tools, other than visual examination and informal interviews, that might be useful to transparency visits
- the competencies required to be present in the visiting team
- the role of CBMs, and the need for them to provide greater detail of dual use activities, particularly when they are politically sensitive.

Abbreviations

BSL	Biosafety level
BTWC	1972 Biological and Toxin Weapons Convention
CBMs	Confidence-building measures
DURC	Dual-use research of concern
EDPs	Especially dangerous pathogens
GHSA	Global Health Security Agenda
GMOs	Genetically modified organisms
GPS	Global Positioning System
HEPA	High-efficiency particulate arrestance
IHR	International Health Regulations
ISO	International standards
ISU	BTWC Implementation Support Unit
NCDC	National Center for Disease Control & Public Health, Georgia
PACS	Pathogen Asset Control System
WHO	World Health Organization