

International Workshop-Training “*Urgent Issues in Protecting Against Biological Threats*”
and 2nd IAG Meeting 17-19 October 2007

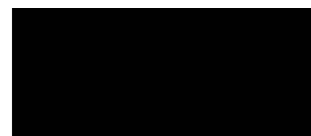
Workshop-Training

Urgent Issues in Protecting Against Biological Threats

17-19 October 2007

I.M. Sechenov Moscow Medical Academy
Moscow, Russia

SUMMARY REPORT



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Technical Report: *Workshop “Urgent Issues in Protecting Against Biological Threats” and 2nd IAG Meeting, 17-19 October*

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I. EXECUTIVE SUMMARY

The International Advisory Group (IAG) held its second meeting of 2007 in Moscow on 18 and 19 October 2007 at the I. M. Sechenov Moscow Medical Academy (MMA). On 18 October an information exchange day was held at the MMA’s Pharmacy Institute for more than 90 participants and on 19 October the second formal meeting of the IAG members in 2007 was held at the Rectorat of the MMA. On the information exchange day participants in addition to the IAG members were invited to present and discuss on topics in the following areas on two parallel sessions:

- Biosafety and biosecurity training and standards; and
- Communicable disease developments in the light of migration and climatic change (including avian flu virus, West Nile virus, tuberculosis and malaria). **see Attachment 1**

This day’s sessions brought new participants into the IAG’s discussions including, in particular, from the Ministry of Defense.

75 Russian experts from 28 organizations and 17 International experts from 12 organizations, that represented 3 countries, including Canada, USA, UK, 3 experts from CIS, Kazakhstan, Kyrgyzia (**see Attachment 3**) attended the Workshop.

At the IAG meeting on 19 October new members and observers were formally approved. In particular, Mr. Terry Duguid of the International Center for Infectious Disease (ICID) of Canada was inducted into the group as a member of the body of international experts. A new member from the UK was also admitted. Provisional nominees from Canada and the UK were also confirmed. New observers from Kazakhstan and Kyrgyzia were formally approved.

A report was given by two Russian members of the IAG on follow-up action taken arising from the IAG meeting in Heidelberg in March 2007. The actions included:

- the submission of comments on the WHO’s draft Biosecurity Guideline (formally submitted by the ICLS on behalf of the IAG); and
- drawing on the Heidelberg meeting and visit to the European Molecular Biology Organisation (EMBO), an intersessional meeting of the Biosafety and Biosecurity Training sub-group was held at Obolensk in June to advance the work on training curricula for the Russian Federation.

A new strategy was agreed for the future conduct of the IAG whereby one meeting of the full IAG (instead of two) will take place each year with more intersessional meetings of the sub-groups.

A proposal was made to host sub-group activities on training (Canada, UK), safe and secure management of culture collections (UK).

IAG member Dr Rainer Wessel (CEO, Ganymed Pharmaceuticals, Mainz, Germany), while not able to attend the meeting made an offer to host a group from the IAG plus additional experts from the Russian private sector to visit Germany under the aegis of Bio-Deutschland of which he is President. The group considered that such a visit would be appropriate for the experts from Sub-Group 4 concerned with regulatory affairs for biotechnological and pharmaceutical facilities including risk management and assessment.

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Proposals were received from representatives of Kazakstan, Canada and Russia to host the IAG annual meeting (November 2008), but after the discussion it was outlined that Russia, Moscow, MMA would be the best venue to bring full Russian participation.

It was proposed (by Vladimir Bundin, MFA, Russia) that the IAG should make a direct contribution to the intersessional work of the Biological and Toxin Weapons Convention (BTWC) on biosafety and biosecurity issues. A suggestion was also made to look into the possibility of the IAG making a technical input (in the form of advice) to the development of the UN Secretary-General’s capacity to fulfill his mandate to investigate alleged use of biological weapons.

The IAG agreed that a major theme for the coming year should be enhancing the link between animal and human health disease surveillance systems. In this connection it was agreed that at least two veterinarians should be added to the IAG’s membership.

A formal offer was received from PulseNet International inviting the IAG to participate in the setting up of a new network to be called PulseNet Eurasia. IAG members are considering this proposal.

II. TRAINING DAY

Participation

A list of participants for the training day on 18 October is in **Attachment 2**. There was an increase in the range of Russian research institutes represented, namely 28 organizations (**Attachment 3**) (In particular for the first time a Ministry of Defense scientific research institutes participated (Virology Research Centre, Sergiev Posad, and Moscow research institute).

Agenda and Discussions

Two broad themes were pursued in the agenda (**Attachment 1**):

- Diseases connected with population migration: epidemiology, prophylaxis and treatment
- Biological safety and biosecurity training

Apart from the opening and concluding session the participants were divided into two working groups, reflecting the two broad themes, in which scientific and technical presentations were given and discussed. At this meeting there was more input on animal health concerns than previously, which highlighted the importance of making stronger connections between the human and animal sectors in terms of surveillance, analysis and organisation. Having two concurrent working groups enabled more presenters to be involved and a wider range of institutions to participate.

The training day was opened by Dr. Julia Ananyina, *Seminar Co-Chairman, Deputy Director, N.F. Gamaleya Institute of Epidemiology & Microbiology*, Terence Taylor, *Seminar Co-Chairman, Director of the International Council for the Life Sciences and President of the Board of Directors*, Dr. Yuri Remnev, *Deputy Executive Director, TEMPO*, Danica Doucette-Preville, *Program Officer, Global Partnership Program, Canada*, Dr. Michael Weaver, *Senior Project Manager, International Science and Technology Center*.

Dr. Julia Ananyina welcomed the participants and said that it is the 3rd international meeting on the issues of biosafety and biosecurity organized by Moscow Medical Academy, ICLS and

TEMPO. The meetings have evolved, and for the first time, the meeting contains a training element. Mr. Taylor stated that the International Council for the Life Sciences (ICLS) is working to enhance biological safety and security around the world by helping to develop and promote international standards and the sharing of best practices. The non-governmental ICLS provides a forum for all sectors of the life sciences community - private industry, academia and government – to identify and manage biological risks whatever their origin. ICLS Priority Action Areas are international biosecurity and biosafety training, best practices and standards, infectious disease surveillance and risk assessment – common approach. Dr. Michael Weaver presented the International Science and Technology Center and welcomed the workshop participants, most of them are the participants of ISTC projects, and the members of the International Advisory Group (IAG). Ms. Danica Doucette-Preville, presented the Global Partnership Program, Ministry of Foreign Affairs and International Trade, Canada, and highlighted that biosafety and biosecurity are the main priority area of the GPP. Dr. Yuri Remnev stated that this workshop training would be the “pilot balloon” for the next step – development of the education program in biosafety and biosecurity and training of specialists in general issues of biosafety and biosecurity. The program will be developed in accordance with the Russian standards and involvement of international experts.

Simultaneous Session #1 – Scientific Lectures

“Diseases connected with population migration: epidemiology, prophylaxis and treatment”

Topic 1. Perspectives in surveillance of highly dangerous pathogens and infections connected with population migration

Moderators

Terry Duguid, *President and CEO, International Centre for Infectious Diseases, Canada*
Vitaly Zverev, *RAMS Academician and Director, I.I. Mechnikov Institute of Vaccines and Sera*

Key points of the session included national current issues of ensuring biosafety and biosecurity in the Russian Federation (RF), surveillance and risk of infectious diseases emergence, novel methods of detection and diagnostics.

Terry Duguid, *President and CEO, International Centre for Infectious Diseases, Canada*, presented his organization – the International Center for Infectious Diseases in Winnipeg, Manitoba, as a unique Canadian organization delivering innovative solutions for the global fight against infectious diseases.

The International Center for Infectious Diseases:

- Bring government, business, academic and not-for-profit organizations together
- New and creative partnerships to fight disease and foster innovation
- Mobilize Canada’s scientific and medical expertise to tackle national and international public health challenges
- Provide management services for



Build capacity

<p>infectious disease initiatives and organizations</p> <ul style="list-style-type: none"> • Build professional and technical capacity in biosafety and biosecurity through education and training • Build national programs and services that connect the infectious diseases community • Assemble and lead domestic and international project teams in innovative research, prevention and treatment • Serve as a point of contact for accessing Canada’s infectious disease expertise 	<ul style="list-style-type: none"> • Offer training courses in biosafety as well as operations and maintenance of high containment laboratory facilities • Provide consulting services for high containment laboratories under development or in operation <p>Mobilize expertise Provide management services</p>
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Natalya Pakskina, *Head of Department of organization for sanitary zones protection, Rospotrebnadzor*, in “Current issues of ensuring biological safety and security in the Russian Federation”, presented current issues of ensuring biosafety and biosecurity in the RF. The legislative documents were outlined - the Law on “Biosafety” (25 July 2002), Prikaz #2194 (4 December 2003) on “Basis of ensuring biosafety and biosecurity in the RF till year 2010 and further perspective”, Governmental decree #64 (9 February 2005) “About governmental committee on biological and chemical safety in the RF”, as well the tasks of the 1st implementation stage of the Federal Target Program “National system of biological and chemical safety in the RF” (2006-2007).

Dr. Neil Simonsen, Infectious Disease Advisor, National Microbiology Laboratory, Canadian Science Center for Human and Animal Health, Public Health Agency Canada, in “Innovations in Surveillance in Canada: The Race for Real Time”, presented Canadian Science Centre for Human and Animal Health, Winnipeg, Manitoba, National Microbiology Laboratory, and outlined it’s role. Very detailed information was given on Canadian Network for Public Health Intelligence (CNPHI), which aims to fill critical gaps in Canada’s national public health information structure by bringing together technical and content experts, focusing on development and implementing *web-based* solutions to enable real-time surveillance, alerting, intelligence exchange and response to critical public health events.

Victor Zavorkhin, *Deputy Head Department, FMBA*, in “Risks of infectious diseases emergence”, presented the main specters of current biological risks of emerging of infectious diseases: risks of diseases connected with migration population, risks of economical activity of population and habitation in the territory of natural locus of infection, risks of natural disasters, and risks of accidents on biological facilities and laboratories. The main preventive measures against risks are: harmonization of legal and normative base in the Russian Federation in the area of biosafety and biosecurity, enlargement of participation of the Russian Federation in the international cooperation on biosafety and bioterrorism counteraction, unification of

requirements for physical safety of microorganism collections, training of professionals in biosafety and biosecurity, constant monitoring and analysis of biological threats.

Dr. Sergey Netesov, *RAS Corresponding member, Vice Rector (Research), Novosibirsk State University/Head of Lab, State Research Center of Virology & Biotechnology VECTOR*, in “Comparative assessment of novel methods of infections’ diagnostics”, gave an overview of novel methods of diagnostics of infection diseases, their characteristics and perspectives of development for next 3-5 years.

WHO: recommended laboratory tests for identification of influenza viruses in samples from patients with acute respiratory disease – August, 2007

- **Real time RT-PCR –test and usual RT-PCR-test for detection of viral RNA and genotyping**
- **Other molecular detection tests**
- **Virological investigation – isolation of virus**
- **Fast antigen detection – immunofluorescence or ELISA**

In the conclusion, it was stated that in case of gene diagnostics the automatization and robotization of the lab process and further improvement of tests will allow to overcome all shortages. Therefore the future of diagnostics of infections is with gene diagnostics.

Dr. Richard Vipond, *General Project Manager, Novel and Dangerous Pathogens, UK Health Protection Agency*, in “Detection of Biothreat Agents on and off-site – the Centre for Emergency Preparedness and Response (CEPR) perspective”, presented the Health Protection Agency, that are

- Combination of Specialist centers and regional labs
- Remit covers Biological, Chemical and Radiological public health issues
- Center for Emergency Preparedness and Response (CEPR) – emphasis on high containment expertise

The attention was made on the activity of the Special Pathogens Reference Unit: field work – which includes collaborative research in Kazakhstan- WHO Collaborative Center for Virus Research and Reference, R&D including diagnostics, biosafety and training.

The unit has a special interest in Crimean-Congo hemorrhagic fevers, hantaviruses and dengue. It conducts molecular and serology based diagnostic tests, with a move towards real time assays backed up by culture. The unit is currently evaluating multiplex chip-based methods for symptomatic driven diagnosis and Point of Contact (POC) detection systems for screening and environmental sampling.

The biosafety unit is responsible for:

- Design, validation and testing of containment equipment;
- Sampling and generation of aerosolized microorganisms and study of their behaviour in test systems and other environments;
- Gaseous disinfection; and

- Quantitative microbial risk assessment.

Simultaneous Session #1 – Scientific Lectures

“Diseases connected with population migration: epidemiology, prophylaxis and treatment”

Topic 2. Diseases connected with population migration: epidemiology, prophylaxis and treatment

Moderators:

Heather Sheeley, *Manager of Safety, Centre for Emergency Preparedness and Response Health Protection Agency*

Dr. Igor Krasilnikov, *Head of R&D Department, Microgen*

Key points of the session included biorisk management and biosafety guidelines and infectious disease control, as the general approaches, and overviews of specific diseases, including surveillance, treatment and prophylaxis for avian flu, tuberculosis, malaria, West-Nile fever, brucellosis.

Stefan Wagener, *Chief Administrative Officer, Public Health Agency of Canada*, in “International Laboratory Biorisk Management Standard Initiative”, informed on the purpose of this initiative –to address the need for a consistent approach to:

- managing biological laboratory facilities
- safeguarding laboratory staff, communities and the environment

The Standard will be based around the current WHO Biosafety and Biosecurity Guidelines

Any gaps identified or necessary updates may be addressed if required (e.g. in the light of new knowledge).

The end product will be valuable for:

- improving laboratory performance
- increase awareness/adoption of management system approaches for biosafety & biosecurity
- internal audit and third-party certification of facilities and management systems
- providing a benchmark in setting requirements for laboratory facilities to manage risks associated with biological materials

The proposed Standard is not intended to replace any national or sub-national regulatory requirements that may apply to the laboratory/facility.

Dr. Vitaly Zverev, *RAMS Academician and Director, I.I. Mechnikov Institute of Vaccines and Sera*, **Dr. Alexander Mironov**, *Deputy Head of Department of preclinical and clinical trials, Microgene*, in “Avian flu vaccine”, presented information on inactivated subunit H5N1 influenza vaccine adjuvanted with aluminum hydroxide (produced by the Research-and-Production Unit “Microgen” affiliate in Ufa) and its clinical trials, as well as on methods of immunological analyses.

Dr. Vitaly Litvinov, *RAMS Academician and Director, Moscow Practical Center of TB Fighting, Moscow Department of Health*, in “Monitoring of tuberculosis: epidemiology, diagnostics, prophylaxis, and treatment”, outlined the specific tasks in the field of bacteriological diagnostics of TB:

- Development of centralized mycobacteriological laboratories
- Upgrading of laboratories and implementation of new techniques
- Decreasing of time for cultural identification of Mycobacterium
- Decreasing of time for detection of Mycobacterium drug-resistance; and
- Providing physicians by secure and actual information

One of the urgent questions of the TB epidemiology and diagnostics is detections of bacteria in very short period. Moscow Practical Center of TB Fighting, Moscow Department of Health, is using not only bacteriological methods with BactecTM MGIT TM 960 techniques, but is widely applying molecular-biological methods, namely PCR techniques, sequencing, biochips for RIF- and ISO-resistant strains (TB-biochip, TB-biochip 2). Biochip analysis takes 2 days instead of 17-35 days by BactecTM MGIT TM 960 techniques and 40-107 days by traditionally bacteriological methods.

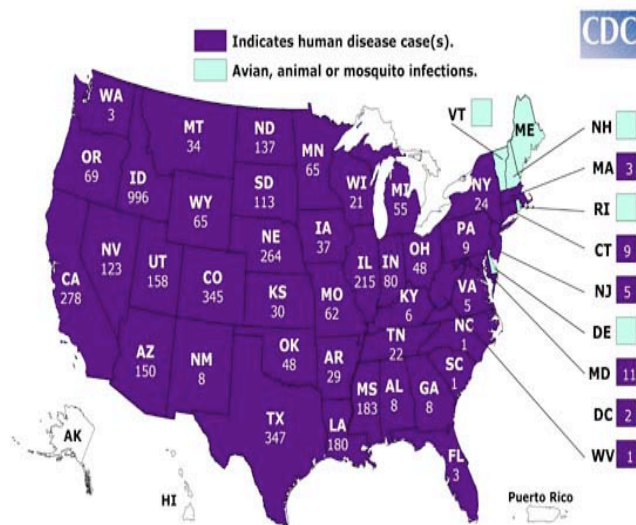
Dr. Eugene Morozov, *Head of Lab, E.I. Martsinovskiy Institute of Medical Parasitology and Tropical Medicine, MMA*, in “Malaria – threats, methods of fighting, prophylaxis and treatment”, informed that malaria is one of the most spread infectious diseases. 400-500 million cases are happened annually. More than 1 million population of the world are lost of malaria. There are several factors of the risk of malaria infection in the Russia: population migration, climate warming, absence of medical preparations, and lack of knowledge on malaria prophylaxis. The situation is getting better since 2004 due to the fact that malaria surveillance system was created. The main aim of the malaria surveillance system is to maintain well-being on the territory in the case of mass infection due to population migration. The key actions are: exposure of malaria infected people, prophylaxis of delivery malaria outside of Russia, raising awareness of malaria among population and methods of treatment, and treatment of reservoirs.

Professor Rysbek Nurgaziev, *Director of Institute of Animal Health, Kyrgyz Republic*, in “Brucellosis in Kyrgyz Republic”, informed on the challenging epizootic and epidemiological situation of brucellosis in Kyrgyz Republic – 1999 - 2.1 cases per 10 000, 2001 - 3.8 cases per 10 000, 2006 - 5.0 cases per 10 000. The main tasks that are facing before the episerice in Kyrgyz Republic are:

- Investigate the prevalence of brucellosis among animals;
- Identify the strategy of brucellosis control;
- Develop the national program of brucellosis control based on recommendations of international experts and veterinaries; and
- Develop and implement the system of a of brucellosis control animals’ identification.

Dr. Sergey Borisevich, *Deputy Chief, Scientific Research Institute, Ministry of Defense-Virology Center, Sergiev Posad*, in “West Nile fever: past and present”, informed on current data on West Nile fever, its main characteristics and epidemiology. Increasing cases of WN virus in the North America is connected with natural migration of wild birds from the Western Africa to

American continent and optimal temperature conditions for virus replication.



Also the increased plasticity of WN virus genome caused the rapid assimilation in new areas – Northern, Central and Southern America. The cases of WNF were registered in Canada, and not only on the south of Canada but also between latitude 500 and 600 north. In the Russian Federation, the high epidemiological situation on WNF is in the South Federal Region – Volgograd, Astrakhan, Rostov and Krasnodar Region.

To ensure the biosafety of population in the Russian Federation, it is needed to perform constant monitoring of WNF not only on the south but also in the middle region.

Dr. Kalia Kasymbekova, Head of National Virology Laboratory, Department of the State Sanitary and Epidemiological Surveillance, Ministry of Health, Kyrgyz Republic, in “Biosafety guidelines and infectious disease control”, stressed that significant changes have taken place in sovereign Kyrgyzstan in state regulation of economy and social relations. The difficult economic situation in the republic aggravates many problems related with the implementation of large scale prophylactic, anti-epidemic and anti-zootic measures. For the purpose of streamlining the operation of biomedical laboratories, ensuring epidemiological safety and preventing accidental or terrorist acts, Article 23 on “Sanitary-epidemiological requirements to work conditions with biological substances and microbiological organisms and toxins” of the Law “On sanitary-epidemiological welfare of the population in Kyrgyz republic” is enforced in the Republic. The following laws were adopted at the national level: Law “On health protection in the Kyrgyz Republic” (09.01.2005), “On sanitary-epidemiological welfare of the population in the Republic” (31.05.2001), “On veterinary” (12.04.2004), “National plan of the Kyrgyz Republic to counteract the highly pathogenic avian influenza pandemic” (16.01.2006), “National Security Concept of the Kyrgyz Republic” (13.07.2001). Approximately 600 diagnostic labs are functioning in the public health system. In 65 labs, belonging to the system of sanitary-epidemiological surveillance, microorganisms are studied for the purpose of detecting and containing dangerous diseases. One of the priorities in the organization and functioning of microbiological laboratories is to create safe working conditions for the personnel and to prevent possible release of the infection from the lab into the environment. Control over the compliance with requirements of biosafety and anti-epidemic regime in labs is imposed on the Republican regime commission of the Ministry of Public Health, on regime commissions in districts and in respective institutions. The Republican Regime Commission inspects conditions in the labs and

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issues licenses to work with microorganisms depending on their hazard level, it checks the qualifications of personnel working with pathogens, their knowledge of biosafety and anti-epidemic requirements, storage conditions and transfers of highly dangerous pathogens.

**Simultaneous Session #2 “Biological Safety and Security Training”
Biosafety, Biosecurity and Risk Management: Roles and contributions of associations and governments**

Moderators:

Dr. Eugene Stavsky, *Head of Biosafety Department, State Research Center of Virology & Biotechnology VECTOR, Rospotrebnadzor*

Heather Sheeley, *Manager of Safety, Centre for Emergency Preparedness and Response Health Protection Agency*

Heather Sheeley, *Manager of Safety, Centre for Emergency Preparedness and Response Health Protection Agency*, in “The Value of Biosafety Associations” gave an overview of national, regional and international safety associations, including the Institute of Safety and Technology in Research (ISTR), the European Biosafety Association, and the International Biosafety Working Group. The ISTR is a UK based national professional association for occupational safety professionals. The membership criteria are high academic excellence and practical experience. ISTR was formed in the 1980s to recognise, promote and develop the specialist role of safety professional in research and technology areas. It has 280 personal members, which are mostly based in the UK but some are overseas (Ireland, Malta). In 2003, the bio group of ISTR was formally recognized. It convenes regular meetings and symposiums on bio-related scientific and biosafety topics, including 3rd generation vectors, genethereapy, animal allergens, and containment solutions, among other topics. The ISTR bio group has an active initiative on biosafety and biosecurity competency curriculum and accreditation of courses and professionals. The European Biosafety Organization (EBSA) has 250 members representing 19 European countries, 4 Asia-Pacific countries, and 2 North American countries. The EBSA mission is to

- Enhance knowledge and understanding of bio safety to prevent harm to man and the environment from biological agents/materials;
- Provide a forum for discussion and debate on bio safety and bio security issues of concern; and
- Promote best practices on biosafety and biosecurity.

The next annual meeting of EBSA will begin with pre-conference courses on 2 April 2008 and the conference from 3-4 April 2008 in Florence Italy.

The mission of the International Biosafety Working Group (IBWG), of which Heather Sheeley is Co-Chair, is to support and promote biosafety on a national and international level through collaboration among national and regional biosafety organizations worldwide. It encourages the formation of national and regional biosafety/biosecurity bodies. The IBWG regularly provides opportunities for materials and documents to be translated into other languages and provides a forum for the exchange of materials, such as training tools, information and guidance. It has an active program to twin (connect) individuals, institutes and organizations and will help identify mentors for interested individuals. Individuals interested in finding out more about these organizations should contact Heather Sheeley or visit the organization’s websites.

Dr. Eugene Stavsky, *Head of Biosafety Department, State Research Center of Virology & Biotechnology VECTOR, Rospotrebnadzor*, in “Biosafety of research laboratories and biorisk management” underlined that there are three biosafety tasks:

- Product safety
- Personnel safety
- Environment safety: (nature and community)

Then he compared Russian Federation regulations, the US BMBL and the WHO LBM.

Research Laboratories BSL-2-BSL-3

Laboratory arrangement and equipment	Biosafety Level according to CDC-NIH, WHO		“Hot” zone for working with pathogens in compliance with the RF Sanitary Rules	
	BSL-2	BSL-3	Groups III-IV	Groups I (except viruses) - II
Laboratory isolation (location)	No	Yes	In a separate building or isolated section of the building	In a separate building or isolated section of the building
Access to laboratory	No restrictions	Restricted	Restricted	Restricted
Lab containment	No	Yes	No. Windows and doors of the “hot” zone should be sealed	Yes
Supply and exhaust ventilation systems	Desired	Yes	Yes	Yes
HEPA or similar filters installed in supply and exhaust ventilation systems	No	A single cascade at air inlet/outlet.	Exhaust system with a single cascade, or without it, if BSC Class II is used	A single cascade at air inlet/outlet
Pre-isolation room (with two doors at the entrance)	No	Yes	Yes	Yes
Personnel changing rooms with air chambers at the entrance/exit	No	Yes	Yes, for newly constructed facilities	Yes
Decontamination shower at the exit	No	No	No	No
Anteroom with shower	No	Yes/No1	Yes, for newly constructed facilities	No
Sanitary shower, personnel washing	No	Yes/No1	Yes, for newly constructed facilities	Yes
Waste water collection and treatment	No	Yes/No1	Chemical decontamination of liquid waste	Yes
Collection and treatment of shower water	No	No	No	Yes
Autoclave at workstation	Desired	Yes	Yes	Yes
Autoclave in laboratory	No	Desired	Yes	Yes
Pre-isolation room (with two doors at the entrance)	No	Yes	Да	Yes
Personnel changing rooms with air chambers at the entrance/exit	No	Yes	Yes, for newly constructed facilities	Yes
Decontamination shower at the exit	No	No	No	No
Anteroom with shower	No	Yes/No1	Yes, for newly constructed facilities	No
Sanitary shower, personnel washing	No	Yes/No1	Yes, for newly constructed	Yes

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			facilities	
Waste water collection and treatment	No	Yes/No1	Chemical decontamination of liquid waste	Yes
Collection and treatment of shower water	No	No	No	Yes
Autoclave at workstation	Desired	Yes	Yes	Yes
Autoclave in laboratory	No	Desired	Yes	Yes
System of air supply to space suites	No	No	No	No
System of disinfection solution production and dispensing	No	Desired	No	Yes
Power supply redundancy (back-up) system	No	Yes	No	Yes
Diesel power generator	No	Yes	No	Yes
Redundancy/back-up of systems, assemblies, equipment	No	Yes	No	Yes
Water supply system	Conventional	Equipped against inflow and reverse flow	Conventional	Equipped against inflow and reverse flow
Vacuum, compressed air and gas supply lines	Conventional	Equipped with cleaning system and HEPA-filters	Conventional	Equipped with cleaning and filtering systems
Alarm system	No	Yes	No	Yes
Fire alarm system and fire extinguishing equipment	Yes	Yes	Yes	Yes
External control system	No	Desired	Yes3	Yes3

Notes: 1 – Depending on pathogens used in the laboratory; 2 – For example, windows video cameras, two-way communication; 3 – windows.

Dr. Stavsky gave information on Biorisk Control (Management) that is managing by three key staff: Laboratory Director, Principal (Senior) Investigators and Biosafety Officer.

Responsibilities of Laboratory Director, Principal (Senior) Investigators are:

- Identification (determination) of the level of agent hazard, initial risk assessment
- Identification (specification) of hazards posed by laboratory procedures
- Final biorisk assessment
- Evaluation of training provided for researchers, technical and supporting laboratory personnel
- Review of conducted biorisk assessment

Responsibility of Biosafety Officer is to review of conducted biorisk assessment

John Campbell, *Research Safety Manager, Ottawa Health Research Institute, Canada*, in “ABSA Canada: A National Organisation for Biosafety Professionals” informed the group about ABSA Canada and the general benefits of biosafety organizations. He also provided information regarding clinical biosafety and his organization. ABSA Canada, an affiliate of the American Biological Safety Association, is dedicated to fostering and promoting biological safety in Canada. The goals of the organization are to

- To encourage research in the area of biological safety;
- To provide a forum for both public awareness and professional development within the discipline of biological safety;
- To establish ABSA Canada as the principal professional organization with respect to biological safety, within Canada; and
- To ensure and maintain the viability of the American Biological Safety Association (and affiliates) as an association of professionals.

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ABSA Canada membership is open to anyone with an interest in biological safety; membership dues are \$35.00 CDN. At present, ABSA Canada has 73 members representing a wide range of professionals with knowledge on laboratory design, containment principals, sterilization and disinfection.

ABSA Canada

- Facilitates communication between biosafety professionals & nurture networking;
- Develops & shares training programmes;
- Helps interpret guidelines & regulations;
- Encourages pooling of resources/comparison of work practices & experiences; and
- Forum to answer questions related to biosafety.

ABSA Canada is an international affiliate of ABSA – the American Biological Safety Association. International Affiliates are independent, international organizations with goals and principles similar to those of ABSA.

- Membership in ABSA is not required for membership in an international affiliate;
- There are no links to ABSA in terms of the Affiliate's charter and management;
- A Constitution and By-Laws for affiliate organisation must be drafted; and
- Dues paid to the affiliate organization and any other financial matters are not the responsibility of ABSA nor are they regulated by ABSA.

Forming biosafety organizations encourages collaboration between government agencies, members of the scientific community, and facility and engineering specialists to define regulations/guidelines and provides a resource of biosafety and biosecurity expertise.

The Ottawa Health Research Institute, an affiliated research institute of the University of Ottawa, is the research arm of the Ottawa Hospital with a staff of over 1300 and an annual budget of \$80 million. Over 1,300 clinical research projects are registered at the Ottawa Hospital.

Training for new clinical research and staff includes

- Clinical Research & Clinical Trials
- Grants Research Ethics
- Department of Pathology & Laboratory Medicine
- Privacy Clinical Trial Agreements
- Biosafety
- Safety Tips For Home Visits

Biosafety is different from infection control. **Biosafety** programmes and procedures are in place to protect staff and the environment from exposure to infectious agents used in a laboratory and other research facilities, while **Infection Control** programmes are designed to investigate, prevent, and control the spread of preventable nosocomial diseases and infections in workers, patients, and visitors within health care facilities.

Dr. Vyacheslav Zhemchugov, Senior Specialist, *State Research Center of Applied Microbiology & Biotechnology, Rospotrebnadzor, Obolensk* /**Dr. Yuri Remnev**, Deputy Executive Director, TEMPO, in “Preparation of educational programs in biosafety and biosecurity for African and Asian countries,” stressed the importance of Russian bilateral relations in cooperation to strengthen public health in the developing world.

In 2006, as the Chair of the G8 summit Vladimir Putin stated, “Infectious diseases cause great harm to the population and to economies of countries throughout the world. We have outlined the principles and actions necessary to stop the proliferation of epidemics. We have discussed a

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whole range of issues, including limited access to prophylaxis and treatment means, inadequate capabilities of health protection systems, insufficiency of resources, as well as the deficit and significant outflow of qualified medical personnel, especially from developing countries”.

In response, Russia has developed a bilateral agreement with Namibia, which states that the Russian side shall provide training in Russian Higher educational establishments of qualified staff for the republic’s public health system, prior to the training process it shall delegate the necessary number of Russian qualified experts. Another element of the agreement is to increase technical support by delegating an additional number of Russian experts, and by arranging for training of national personnel in Russia on a permanent basis.

The management of the State Scientific Center for Applied Microbiology and Biotechnology, the Moscow Medical Academy and TEMPO have agreed to collaborate to design a training course on biosafety and biosecurity for students and physicians both from Russia and foreign countries. It is proposed that theoretical and practical classes will be conducted by experts from the chairs of microbiology and infectology of the MMA, from the Applied Microbiology Center and presumably from other institutions. For practical classes in real BSL 2-4 conditions a special training facility will need to be built on the premises of the Center for Applied Microbiology, which will be operated by a team of professionals and will take into account the long-term experience of the Russian anti-plague system and of CDC (USA).

The facility will include functioning premises of main areas of specialization:

- diagnostic microbiological, virological and serological laboratories of BSL 2-4 levels, including mobile labs;
- in-patients ward for patients suspected to be infected with groups 1-4 pathogens;
- production premises, meeting GMP requirements, for production of biomass (yeast) and medications (saline vials);
- vivarium, meeting GLP standards;
- storage for cultures of 1-4 groups of pathogenicity;
- medical station for personnel supervision;
- classrooms for theoretical classes;
- the building will have real physical protection barriers and will operate in accordance with real biosafety and biosecurity requirements; and
- protected transportation vehicles for transporting patients.

**Simultaneous Session #2 “Biological Safety and Security Training”
Biosafety, Biosecurity and Risk Management**

Moderators:

Barry Holmes, *UK National Collection of Type Cultures*

Petr Deryabin, *Deputy Director, D.I. Ivanovsky Institute of Virology*

Barry Holmes, *Head of the UK National Collection of Type Cultures*, in “Evolution of the NCTC and the culture collections network throughout the world,” informed about the history of culture collections, current practices, and future trends.

The NCTC, established in 1920, was the first collection in the world to offer a supply service of bacterial cultures. At present there are nine national collections in the UK, including cell cultures, pathogenic viruses, medically important fungi, and medically important bacteria. All are consolidated within the Health Protection Agency Culture Collections (HPACC). NCTC is certified to BS EN ISO 9001:2000 and the scope of its accreditation is the maintenance and supply of bacterial cultures.

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The European Culture Collection’s Organization includes 65 culture collections in 24 countries, with six of these located in the Russian Federation. Members of the World Federation for Culture Collections (WFCC) represent 525 culture collections in 67 countries, 13 of these in the Russian Federation. The WFCC holds international congresses every three years. The Organization for Economic Cooperation and Development (OECD) in 2001 documented a need for culture collections to evolve into Biological Resource Centres holding much of this data and to form a global network.

The NCTC provides:

- Over 5,000 cultures of medical, scientific and veterinary importance;
- Cultures supporting accreditation requirements;
- Over 100 mycoplasmas;
- Over 500 plasmids, host strains, bacteriophages and transposons;
- The most popular cultures from the NCPF collection;
- Freeze-drying services; and
- Services of an International Depository Authority for patent strains.

Its current initiatives are to:

- Develop a new web-based searchable catalogue, containing not only traditional catalogue entries for each culture, but also phenotypic characters, rRNA sequences and other data – www.nctc.org.uk;
- Develop of an integrated web site for the HPACC; and
- Promotional literature, trade shows.

Methods of bacterial preservation, quality control, ongoing monitoring, the need to supply and transport microbial cultures and relevant regulations were also discussed.

Dr. Victor Bezsmertny, *Chief Physician*, **Dr. Yuri Khomyakov**, *Head of Lab, Antiplague Center, Rosпотребнадзор* in “Issues of safe shipment of biological agents in Russia”, gave an overview of the Russian Federation regulations governing the transport of biological agents. He informed on Federal Law “On Sanitary and Epidemiological Well-Being of the Public” (1999), that includes

- The conditions of work with biological and microbiological organisms and their toxins ... with infection agents should not cause harmful effects in humans
- Requirements to ensuring safety of work conditions ... for humans and environment shall be established by sanitary rules and other legislative instruments of the RF
- Compliance with the sanitary rules is mandatory for nationals, individual entrepreneurs and legal entities

Then he informed on Sanitary and Epidemiological Rules - legislative instruments, establishing criteria of safety and harmlessness of environmental factors for humans and requirements for ensuring favorable conditions for their life activity, Instructional guidelines and Guidelines. Guidelines consist:

- ▶ Guidelines on conducting work in diagnostic laboratories, using polymerase chain reaction (PCR) method. Basic provisions
- ▶ Collection, shipment, and storage of clinical samples for PCR diagnostics.

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- ▶ Organization of monitoring of avian flu exports and outspreads under the natural conditions in the RF territory
- Copies of forms that need to be used were also shown electronically. Regardless of risk group, the movement of all biological agents is monitored and tracked.

At the end, Dr. Khomyakov gave an information on results expected in 2008-2013 from the implementation of IHR (2005). There are the following:

- ▶ Reduction of economic and social burden as well as public health burden caused by infectious diseases;
- ▶ Availability of equipment, technology, guidelines, and experience of systematic organization of activities and cross-sectoral cooperation in the countries and international community for detection, assessment and response to global emergencies;
- ▶ Establishing of norms and standards in the course of development of the national plans and alert state for counteracting global emergencies on a regular and accidental basis;
- ▶ Establishing of national norms and standards in epidemiological surveillance and methodology of data collection, processing, mapping and interpretation in compliance with the IHR requirements (2005);
- ▶ Development of WHO-compliant Standard Operating Procedures to manage acute health threats in all agencies.

Guy Collyer, *National Counter Terrorism Security Office* in “Biorisks - Influencing Factors: How other incidents can directly impact the laboratory,” informed about recent events in the UK and elsewhere and their implications for biosafety and biosecurity. Background information was given on the Aum Shrinrikyo attacks in Japan and the anthrax letters in the United States. Two recent events in the United Kingdom were also mentioned, the suicide bombing at the Scottish airport and the FMD outbreak.

The individuals involved in the suicide bombing were all employees of the local hospital. This brings up the related issue of personnel security and screening practices. The FMD outbreak was caused by individuals failing to follow basic practices.

Dr. Vasily Kholodenko, *Senior Specialist on Biosafety, State Research Center of Applied Microbiology & Biotechnology, Rospotrebnadzor, Obolensk* in “Biosafety Problems for Developing Nanotechnology” gave an overview of nanotechnology, its importance to the Russian Federation and implications for biosafety. According to the *Journal of Nanotoxicology*, over 10 million people will be engaged in nanomaterial production by 2014, and, therefore, a potential risk of nano-dimension structures should be considered today. An example of current research was given. Professor Sungho Jin and his colleagues (University of California, San-Diego, UCSD) have found that nanoparticles damage *in vitro* cells PC12 derived from nerve tissues of rats.

According to expert estimates, there are 5 key tasks to solve to make any nanotechnology safe:

- Elaborate a program of systematic research to determine potential nanoparticles-associated risk.
- Develop methods of detection of nanoparticles in air and water environments.
- Develop methods of assessment of potential toxicity of nanomaterials.

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– Design a model allowing the prediction their possible impact on the environment and people health.

– Develop a method to assess influence of nanoparticles on the environment and people health.

In some EU countries, as well as in the USA, a normative & methodical base for assessing safety of production and application of nanotechnological products is under elaboration.

Based on Mr. Ohishchenko’s notice, Head of Rospotrebnadzor, of May 2, 2007 on «Surveillance of Production and Turnover of Nanomaterial-Containing Products», in May 2007 by the order of Dyatlov I.A., Director of SRCAMB, a work group to prepare information-and-analytical materials and proposals relating to the involvement of the Center into carrying out complex research in the field of biosafety of nanomaterials and nanotechnologies was established.

Main Tasks of the Group:

- Elaborate a concept of toxicological research
- Elaborate methodology of the risk assessment
- Develop methods of identification and quantification of nano-materials and -particles
 - Prepare proposals on setting up an information-and- analytical center to study aspects of biosafety of nanotechnologies and nanomaterials

In the framework of inter-institute cooperative activities and international projects SRCAMB is carrying out research on:

- · - Ig nanolayers in bacterial sensors;
- · - Biological activity of nanoparticles conjugated with anti-tuberculosis formulations;
- · - Bactericidal effects of titanic nanomaterials as implants.

Dr. Nikolay Staritsyn of Booz Allen Hamilton gave an overview of the U.S. Department of Defense activities to help promote and train biosafety officers at Russian institutes.

III. IAG MEETING

The meeting convened the members of the IAG and observers.
The following issues were discussed:

Report on the Heidelberg Meeting

Dr Kholodenko and Deryabin reported on the IAG meeting in Heidelberg in March 2007 alongside the European Biosafety Association (EBSA) annual meeting. They rated highly the special session with the European Molecular Biology Organisation (EMBO) and their associated laboratories (EMBL). The visit to EMBO and EMBL was a new experience for all the Russian and Central Asian members and the scientist-to-scientist exchange was greatly valued. Participation in the training sessions at the EBSA meeting was considered extremely useful and directly relevant to their concerns. They reported on the IAG meeting that immediately followed the EBSA conference. In particular they reminded the group that the IAG’s consolidated comments, agreed at the meeting, on the WHO’s draft Biosecurity Guidelines was a significant achievement. The comments were submitted formally by the ICLS to the WHO whom expressed their appreciation for the IAG’s input.

Report on Intersessional Activities

Dr Kholodenko also reported on the intersessional meeting of the IAG’s Sub-Group 2 on Biosafety and Biosecurity Training. He said this meeting was very much inspired by the Heidelberg IAG meeting and the sessions at EMBO and EBSA. The meeting was held at Obolensk and chaired by the Director and IAG member Dr Ivan Dyatlov. Dr Kholodenko reported that the meeting was fruitful in making progress on developing national training curricula for biosafety and biosecurity through drawing on the international experience and applying it in the context of Russian laws and regulations. The group felt that intersessional sub-group activities should be more intensively pursued.

Proposal for a PulseNet Eurasia

PulseNet International asked the IAG to consider participating in setting up a PulseNet Eurasia as part of their global network for rapid identification and international comparison of certain bacteria strains, in order help in deploying a timely public health response, in the event of outbreaks of salmonella, shigella, listeria and similar infections. PulseNet International is the coordinator of six regional networks (Asia-Pacific, Canada, Europe, Latin America, Middle East and USA). Russia and Central Asia represent one of the gaps in the global coverage. A letter was received from PulseNet International by the Co-Chairman that was circulated to IAG members at the meeting. PulseNet International offer assistance with training and acquisition of the necessary equipment (Pulsed Field Gel Electrophoresis (PFGE)). The organisation operates under the aegis of the US Centers for Disease Control and is a non-commercial organisation. PulseNet International also provided copies of presentations in English and Russian, explaining the organisation of PulseNet and the operation of the PFGE equipment that were circulated to IAG members. Members were asked to submit their views on the invitation and an expression of interest or otherwise by 15 December to the TEMPO staff.

Future Strategy and Plans

The Co-Chairmen proposed a new strategy for the work of the IAG for 2008. The proposal was to move from two full meetings of the IAG each year to one, and to promote more intensive work by the sub-groups. The purpose of the change is to encourage productive work through scientist-to-scientist cooperation on topics with a clear focus. The group agreed this strategy. The next full meeting of the group was proposed for November 2008. Three offers to host the meeting were received from Kazakhstan (Dr. Ramanculov), Canada (Mr Duguid) and Russia (Dr. Remnev). Discussion after the meeting between the Co-Chairman, Mr. Duguid, Dr. Ramanculov and Dr. Remnev resulted in a shared view that Russia, MMA, Moscow, would be the best venue. Particular consideration was to gain more assurance of full Russian participation. Canada and Kazakhstan could make vital contributions by hosting intersessional sub-group activities.

Members felt that an important theme for the coming year, including at the next full meeting of the IAG, should be the need to strengthen the links between animal and human health organisations and activities. As noted in the Executive Summary it was agreed that at least two more veterinarians should be brought in as members of the group. Dr Julia Ananyina (Gamaleya Institute) offered to seek appropriate candidates in Russia and make proposals accordingly.

IAG members shared suggestions with respect to future work of the IAG. Canadian member Stefan Wagener emphasized that the group needs to retain its focus on biosafety and biosecurity and conduct activities with deliverables when possible, in order to help measure the success of the Group.

BTWC and the UN

It was proposed (by Vladimir Bundin, MFA, Russia) that the IAG should make a direct contribution to the intersessional work of the Biological and Toxin Weapons Convention (BTWC) on biosafety and biosecurity issues. A suggestion was also made to look into the possibility of the IAG making a technical input (in the form of advice) to the development of the UN Secretary-General’s capacity to fulfill his mandate to investigate alleged use of biological weapons.

Nanotechnology

Dr Kholodenko, supported by Russian colleagues, proposed that the IAG should include in its future agenda the biosafety and biosecurity aspects of developments in nanotechnology. Views on broadening the agenda in this way were divided. Dr. Kholodenko was asked to submit a short paper by 15 December to the IAG outlining the issue and how it might be dealt with by the group.

Translation and Communication

The IAG stressed the importance of translating key documentation from Russian into English and vice-versa as a vital element in enabling the work of the group.

Infectious Disease Subgroup

Dr. Sergery Netesov informed the group of the absence of Drs. Lvov and Tkachenko from the meeting. He offered to convene a meeting with them by December 15 to discuss a variety of issues, including ideas for intersessional work.

Subject to confirmation by the governments and organizations concerned, and of funding support, the following proposals were made for intersessional sub-group activities:

1. Dr Heather Sheeley proposed a visit and training session by members of Sub-Groups 2 (training) and 3 (safe and secure management of culture collections) at the UK’s Health Protection Agency’s facilities at Porton Down
2. Mr. Terry Duguid proposed a visit and training by members of Sub-Group 2 and others as appropriate. The proposal is that the group would visit the Public Health Agency’s facilities in Winnipeg. Mr. Duguid pointed out that since both animal and human health facilities were operated at this site, in addition to the training, fruitful work could be done by a seminar on the animal and human health nexus.
3. IAG member Dr Rainer Wessel (CEO, Ganymed Pharmaceuticals, Mainz, Germany), while not able to attend the meeting, made an offer (via ICLS) to host a group from the IAG plus additional experts from the Russian private sector to visit Germany under the aegis of Bio-Deutschland of which he is a member. The group considered that such a visit would be appropriate for the experts from Sub-Group 4 concerned with regulatory affairs for biotechnological and pharmaceutical facilities including risk management and assessment. The IAG members recommended participation in this activity by appropriate experts from the private sector from participating countries. Dr. Igor Krasilnikov of Microgen has agreed to be involved in such a meeting and will assist in identifying other relevant Russian participants from outside the IAG.

Those making proposals were encouraged to submit firm dates and programmes as soon as practicable.

New Members and Observers

The following decisions were taken:

- New members accepted as members of the body of international experts:
 - Terry Duguid, President and CEO, International Centre for Infectious Diseases, Canada;
 - Dr Richard Vipond, General Project Manager, Novel and Dangerous Pathogens, UK Health Protection Agency;
 - Guy Collyer, National Counter-Terrorism Security Office, UK (moved from observer status).
- Provisional members confirmed:
 - Dr Stefan Wagener, Science Director, Canadian Science Centre for Human and Animal Health, Public Health Agency of Canada

New observers from Kazakhstan and Kyrgyzia:

- Dr. Erlan Ramankulov, General Director, National Biotechnology Center,
- Dr. Rysbek Nurgaziev, Director, Kyrgyz Rsearch Institute of Cattle, Veterinary and Pasture,
- Dr. Kalia Kasymbekova, Head of National virological laboratory, Department of the State Sanitary & Epidemiological Surveillance, Ministry of Health

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It has been proposed that the IAG should adopt a formal policy with respect to new members and expansion.

The meeting was brought to a close and IAG members were welcome to stay for the 5 year review of TEMPO’s activities.

IV. ACTIVITIES REPORT

Preparation the Workshop materials

- An agenda was developed on time. The program included on 18 October a training day that was held at the MMA’s Pharmacy Institute for more than 90 participants and on 19 October the second formal meeting of the IAG members that was held at the Rectorat of the MMA. **Attachment 1.**
- The IAG Newsletter was developed in coordination with the ICLS and then issued. **Attachment 4.**
- The participant’s folder was developed and issued (**Attachment 5**).

Development Russian participants list and provide logistical support to them:

The list of Russian participants was developed on time (**Attachment 2 & Attachment 3**). 20 Speakers (7 Non-Russian, 2 CIS and 11 Russian) as well as moderators were defined for the training day on 18th October. The letters of invitation, signed by Academician Mikhail Paltsev, were distributed. TEMPO assisted in travel arrangements for 10 participants from Novosibirsk region (VECTOR), St. Petersburg, Kazan, Kazakhstan and Kyrgyzia. The presentations from speakers were collected by TEMPO and submitted for the translation. The CD of presentations was submitted to the ISTC.

Local transportation’s support to the International Experts:

The transportation support was provided by TEMPO to the international experts: pick-up from the hotel to and from the workshops’ venue for 3 days – 17-19 October.

Preparation and printing of hand-outs

The program was designed and printed out on Russian and English. IAG Newsletter (**see Attachment 4**) was designed and typed on Russian and English. The folder was designed and printed (**Attachment 5**).

Event Promotion

The report, made by the I.M. Sechenov Moscow Medical Academy’s Press Center, is attached (Attachment 6, prepared by the Press Center). The following mass-media companies have attended, among them representatives of the informational agency gazeta.ru, special medical press - Medical Vestnik, Medical Newspaper, also the press photographer worked. The more publications are coming soon in November-December. TEMPO made the announcements on its web site (www.nptemp.ru). The report on the Workshop, on Russian and English, is placed on TEMPO web site.

Conducting 2-days Workshop:

17 October – Working Dinner for IAG members and invited guests. Get-together event was held at the Central House of Scientists, that brought about 30 International (Canada, US, UK), CIS and Russian experts to continue a dialog on common issues of biosafety and biosecurity.

1st training day on the 18th October – two parallel sessions in conference-hall and classroom

2nd day on the 19th October - 2nd IAG meeting

The task was fulfilled completely. The Workshop was organized and arranged without any delays. The Workshop facilities (Institute of Pharmacy, I.M. Sechenov Moscow Medical Academy, conference-hall and classroom, and MMA Rectorat building, the rectorat meeting hall on the 4th Fl.) were provided by all necessary equipment (computers, multimedia support, microphones) and maintained properly. The technical assistance was provided for simultaneous translation (equipment, interpreters, materials, presentations). The working dinner, coffee breaks, lunches, dinners were arranged on time and properly by TEMPO for the Workshop performance.

In conclusion, all tasks were fully accomplished.

Project Manager

Yuri Remnev
NP TEMPO Deputy Executive Director