

Report of the World Health Organization (WHO) Biosafety Inspection Team of the Variola Virus Maximum Containment Laboratories to the State Research Centre of Virology and Biotechnology ("SRC VB VECTOR"), Federal Service for Surveillance on Consumer Rights Protection and Human Well-being, Novosibirsk

Kol'tsovo, Novosibirsk Oblast', Russian Federation 30 November – 4 December 2009

# **EXECUTIVE SUMMARY**

The WHO Inspection Team visited VECTOR in order to conduct an inspection of one of the two authorized repositories of live variola virus with the aim of ensuring that the conditions of storage of the virus, and that the research done in the laboratories meet the highest requirements of biosafety and biosecurity, as mandated by the World Health Assembly in resolution WHA60.1. That same resolution also strongly reaffirmed the decisions of previous World Health Assemblies that the remaining stocks of variola virus should be destroyed. The team, in agreement with VECTOR, used a new Laboratory Biorisk Management standard for the assessment. The protocol used was based on the CWA 15793 Biorisk Management Standard.

The WHO inspection team was satisfied with the security and safety arrangements for maintaining, and working with, live variola viruses within the Maximum Containment BSL-4 (Biosafety Level-4) Laboratory and its associated facilities. The VECTOR BSL-4 facility was assessed to have the capacity to conduct work safely with live variola virus as it stands.

Although a number of recommendations have been made, the WHO inspection team found that VECTOR implements appropriate levels of biosafety and biosecurity for its work with variola virus.

A positive finding was that VECTOR staff recognizes the need for a policy and process of constant improvement of biosafety and biosecurity systems at VECTOR.

The WHO inspection team recommended that VECTOR staff collaborate with CDC (Centers for Disease Control and Prevention) staff and WHO experts in order to establish a tool for future WHO biosafety inspections of the two repositories based on the CWA 15793 Biorisk Management Standard.

In summary, the WHO inspection team found the VECTOR Maximum Containment BSL-4 facility to be safe and secure for the work with live variola virus.

## CONTEXT

- 1. The WHO inspection team visited the State Research Centre of Virology and Biotechnology VECTOR in order to conduct an inspection of one of the two authorized repositories of variola virus. The team also inspected the facilities of the Medical and Sanitary Unit 163 of the Russian Federal Medical and Biological Agency, which provide medical coverage and emergency response capabilities for staff working in VECTOR's Maximum Containment laboratories.
- 2. The aim of the visit was to ensure that the conditions of storage of the virus and the research done in the laboratories meet the highest requirements of biosafety and biosecurity, as mandated by the World Health Assembly in resolution WHA60.1. That same resolution also strongly reaffirmed the decisions of previous World Health Assemblies that the remaining stocks of virus should be destroyed.
- 3. Staff from VECTOR had participated in the WHO inspection of the Maximum Containment Facility at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, United States of America, in March 2009. To maintain parity through the use of a common set of criteria for the inspection, the WHO team agreed that the new Laboratory Biorisk Management standard, developed through the European Committee on Standardization (CEN) and which had been used in the CDC inspection, would also be applied in the inspection of the maximum containment facilities at the VECTOR centre.

#### INSPECTION PROGRAMME

- 4. The inspection took place over four days, with a presentation and discussion of the draft report on the fifth day. Both VECTOR staff and the WHO team stressed their commitment to the safety of the researchers and other workers in the facility and to ensuring, as noted in resolution WHA60.1, that the conditions of storage of the virus and for research conducted in the laboratories fully met the requirements for biosafety and biosecurity.
- 5. It was also noted that, as in the case of the report of the inspection team of the CDC facility and in accordance with resolution WHA60.1, the final report of the team would be made public, after redaction for scientific clarity and consideration of security issues. The timing of the visit was important not only in view of the imminent review of research on variola virus in 2010 for the report to the Sixty-fourth World Health Assembly in 2011 but also the close scrutiny being given by WHO's Member States to the public reports of the inspection team.
- 6. The WHO team introduced the assessment instrument, whose aim was to assess biosafety and laboratory biosecurity, thereby increasing transparency, consistency, objectivity and reproducibility in the inspection process. The tool comprises 16 elements concerning management of biorisk, and the team also addressed a specific element on variola virus research. The process consisted of discussions, interviews, programme verification (for instance, checking of records and documentation) and site inspections.

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<sup>&</sup>lt;sup>1</sup> Resolution WHA60.1, operative paragraph 4(5).

- 7. Visits were made to several locations on the site of the Maximum Containment laboratories before the team reconvened for discussions. The fourth day included a visit to the dedicated isolation hospital of Medical and Sanitary Unit 163, which has its own suite of laboratories. The hospital is located on the site and is designed for the management and care of individuals with suspected or actual cases of infection with highly dangerous pathogens. On the fifth day a draft of the report was presented for review and comment.
- 8. VECTOR staff recognized that, as the assessment instrument was generic, it could and should be adapted to the needs of the Russian federal authorities. Proposals to improve and harmonize inspection procedures would be welcome. In this regard it was proposed that, following the experience of the inspection of the CDC facilities earlier in the year and the present inspection, a structured document on the principles of organizing and conducting such inspections be prepared.

#### **GENERAL COMMENTS**

The WHO inspection team was extremely impressed by the consistent and substantive involvement of senior-level management of VECTOR in the entire WHO inspection, reflecting a genuine commitment to continually improve institutional biosafety and biosecurity. In particular the team noted the extensive involvement of the Director-General and the presence of representatives of the Federal Service for Surveillance on Consumer Rights Protection and Human Well-being (Rospotrebnadzor) and of VECTOR's external oversight body (the Territorial Branch of Regional Office 25 of the Federal Medical and Biological Agency).

- 9. It was clearly stated that relevant Russian federal regulations and rules were paramount to the operation of VECTOR's research work.
- 10. The inspection team complimented VECTOR on its response to previous recommendations, including the improvements on clear signage of the facilities and to the overall treatment of the flooring and walls within the Maximum Containment Laboratory.

# APPLICATION OF THE ASSESSMENT INSTRUMENT Biorisk management system

- 11. The WHO inspection team noted that both VECTOR and CDC accepted the use of the CWA 15793 Biorisk Management Standard as an applicable standard, but that both institutes feel that its application in the inspection process can be improved. The team therefore recommends that VECTOR staff collaborate with CDC staff and WHO experts familiar with the Standard in order to establish a tool for future WHO biosafety inspections of the two repositories. Such a tool would clarify documentation, procedural, and/or other requirements for each facility before and during future WHO inspections.
- 12. The system of documentation was found to be both comprehensive and well maintained. Records examined were well maintained, comprehensive and up to date.

- 13. According to an existing procedure, members of staff prior to starting work at VECTOR sign that they have read and understood the relevant regulations and instructions.
- 14. Rospotrebnadzor and VECTOR continue to give strong emphasis to training on biosafety. On the VECTOR site, there is a dedicated unit and facility, and training staff have developed their own audio-visual material (see paragraph 25 below). Specific additional programmes for biosafety specialists (for example on decontamination of rooms) are being designed for staff members working in the relevant buildings of VECTOR. All such courses are based on six seminal documents: the
  - WHO Laboratory Biosafety Manual, 3rd edition, 2004;
  - five Russian Federation regulations, including the Federal Law on Human Sanitary and Epidemiological Welfare dated 31.03.1999;
  - Sanitary Rules SR 1.3.1285-03 "The safety of work with microorganisms of I II pathogenicity (hazard) groups";
  - Sanitary Rules SR 1.3.2322-08 "The safety of work with microorganisms of III IV pathogenicity (hazard) groups and agents causing parasitic diseases";
  - Sanitary Rules SR 1.2.036-95 "The order of accounting for, storage, transfer and transportation of microorganisms of I-IV pathogenicity groups";
  - Sanitary and Epidemiological Rules 1.2.1318-03 "The order of issuing a sanitary
    and epidemiological conclusion on the possibility of conducting work with agents
    of I-IV pathogenicity (hazard) groups, causing human infectious diseases, with
    genetically modified microorganisms, poisons of biological origin, and
    helminths".

Other courses, including recent ones on influenza (H1N1) 2009, contain large elements on biosafety. The WHO inspection team was informed that VECTOR is currently reviewing rules and guidance on biosafety issued in Canada, the United States of America, the United Kingdom of Great Britain and Northern Ireland and by WHO.

- 15. The Territorial Branch of Regional Office 25 of the Federal Medical and Biological Agency of the Russian Federation acts as an external oversight and regulatory authority. It receives copies of the programme of work with variola virus in advance of any work being undertaken in VECTOR and then draws up a schedule of (unannounced) biosafety audits. Its report and recommendations are sent to the Director-General of VECTOR.
- 16. The facility is subject to inspections by VECTOR personnel (internal inspections) and also by Regional Office 25 (external inspections). Inspections and audits were found to be well planned and structured, with structured reporting and closing out of any issues raised. The representative of Regional Office 25 informed the WHO Inspection team of the fact that no accidents or incidents have occurred during VECTOR's work with variola virus and that the setup of work and ensuring biosafety compliance in handling this virus is in accordance with the applicable national legislation.

- 17. The head of each department receives a copy of the manual on organization and performance of work with variola virus in the Maximum Containment BSL-4 Laboratory, approved by the Director-General, and has the responsibility for making all his or her staff aware of its contents. There are indications that this responsibility is fulfilled; indeed the information forms the basis for annual and more frequent refresher courses and examinations.
- 18. Before any research work on variola virus can be performed, biosafety requirements are specified in official documentation (reports on tests performed on engineering biosafety systems; the order on convening a committee on biosafety knowledge assessment; records of knowledge assessment by the committee; and the order on personnel work authorization and initiation of work with variola virus). Copies of the documents were seen by the WHO inspection team.

#### Risk assessment

- 19. The "Explanatory Letter" sent to Rospotrebnadzor is equivalent to a biosafety assessment. This letter details the level of training of personnel, personal protective equipment and clothing required, and the movement of infectious material. It is linked to a specific organism and laboratory. If any condition changes VECTOR submits a new explanatory letter. The permission is called the Sanitary-Epidemiological Conclusion, which provides specific permission to work with variola virus.
- 20. In addition to complying with Rospotrebnadzor's mandated policies, VECTOR has also produced a risk assessment document on the work with variola virus. The inspection team considered this to be an excellent initiative; it commended VECTOR for its efforts and encouraged it to develop risk assessment approaches further. Potential areas for application could include the forthcoming move of the repository, work with animals and security-related assessments.

#### Pathogen inventory and information

- 21. Preparations for the transfer of the collection of stocks of variola virus and variola viral DNA into the building containing the Maximum Containment BSL-4 facility in January 2010 have been made.
- 22. Data were reported on the variola virus collection at the VECTOR centre.

# **General safety**

23. Chemical safety. The WHO inspection team noted that the entrance to the chemical storage area was appropriate in the areas for preparation of the disinfectant, and that chemical protective clothing was available. However it was suggested that further consideration should be given to adding the following safety measures, complementary to Russian regulations. Facilities for washing eyes and emergency water showers to remove chemicals through accidental contact should be provided, and these facilities should be regularly tested to ensure proper working order. Stock chemical canisters should be stored away from preparation areas and isolated above the floor, in case of flooding or

spills. The working procedures and equipment used by the staff testing caustic solutions should be periodically reviewed by senior supervisors.

24. The two-person rule is observed at VECTOR and in the isolation hospital unit in MSU 163.

## Personnel and competency

- 25. A specific unit in VECTOR undertakes modular methodological training programmes, which are approved at Rospotrebnadzor. It runs a four-month postgraduate diploma course on the theory and practice of working with highly dangerous pathogens, and a 72-hour programme specifically on biosafety (when run recently, the course included high-level speakers from WHO and relevant Russian Federation agencies). Staff have to attend periodic refresher courses, and undergo annual testing and certification for their knowledge of procedures and regulations; the results are included in the staff member's personnel file. All members of staff are informed about the health hazards relating to infection with dangerous pathogens and the necessary responses. A further examination is given to staff members who use protective suits. The highest level of training in biosafety in the country, both theoretical and practical, is that given at VECTOR.
- 26. Among their responsibilities, information technology personnel ensure security of data and protection against hacking and other attempts to obtain electronic information. They train and develop their expertise at both VECTOR and other locations.

## Good microbiological technique

27. Although it appears that good microbiological practices pertain, the team had no opportunity to examine this aspect. However, the team did see training manuals and a BSL-2 training laboratory.

#### Clothing and personal protective equipment

28. The team was informed of the fact that new positive-pressure suits will be introduced within the next two years. The currently-used positive-pressure suits are robust and the team looks forward to inspecting the Russian-designed replacements.

#### **Human factors**

29. Supervisors monitored staff for behavioural and psychological characteristics, and every five years staff are examined by a behavioural psychologist. A collective approach is applied towards breaches of working practices; any such incident is discussed by the team and the whole team has to have its knowledge of working practices reviewed. Any major breach of practice is analysed and the results are transmitted to all equivalent institutions in order to prevent any recurrence. In order to encourage openness and transparency, staff are not administratively punished for technical breaches that resulted in an accident. Staff demonstrating good practice may be rewarded. In the case of a staff member who makes repeated errors in laboratory practice, however, dismissal is possible.

#### Health care

- 30. In the case of a member of staff who fails to report for work or is absent for more than two hours, VECTOR's rules specify the actions that have to be taken to investigate the incident. This provides an additional means of raising awareness among staff.
- 31. The inspection team was provided with reports of VECTOR having access to, and in some cases using, new approaches to vaccinating against smallpox. These methods would be of significant interest to the larger world health community, and the inspection team encourages the responsible authorities to publish the available data relating to the safety and efficacy of these new smallpox vaccines.
- 32. The inspection team reviewed the special medical facilities that are available for housing potentially infected personnel. It was confirmed, by both MSU-163 and VECTOR staff, that all smallpox diagnostics will be performed under BSL-4 containment. The inspection team asks that a statement be provided to WHO saying that this smallpox diagnosis strategy will be recognized as being performed by an accredited body and the results of such work (confirmatory identification) would be legally acceptable to the Russian public health authorities.
- 33. It was confirmed that, in order to minimize any potential contamination of healthcare providers by patients potentially exposed to variola virus, health-care providers would exit from the patient area to the adjacent room in a unidirectional (i.e. one-way) manner. That is, health-care providers will not return to the patient area after exiting into the adjacent room where they decontaminate and remove their pneumatic (positive-pressure) suits. This one-way direction of travel of health-care providers is an acceptable procedure for infection control, as it minimizes the potential for infection of non-infected personnel in adjacent areas. The team did not have an opportunity to view the facility under operating conditions, or with the air handling system operating, but it was confirmed that the patient areas exhibit the greatest pressure differentials when in operation.

### **Emergency response and contingency planning**

34. The team was informed that procedures are documented for responses to an emergency, and reviewed the texts.

## **Accident and incident investigation**

- 35. All accidents have to be reported, by law. An algorithm for the obligatory investigatory and reporting process forms part of the training programme and was seen by the inspection team. Once the incident is reported, its seriousness is determined and the response is graduated accordingly.
- 36. A formal accident-investigation process is in place with investigations carried out by an external commission, structured reporting forms and other good practices. There

are additional examples of good practice related to this area, including internal occupational health and safety inspections, and the opportunity to send memoranda regarding potentially dangerous situations. It was also recognized that there may be further opportunities for development of systems in terms of collecting and analyzing data from incidents in line with good practices described in CWA 15793, and the desire to continue to consider such approaches and to continual improvement in general is commended.

# **Facility physical requirements**

- 37. The WHO inspection team commends VECTOR on the state of the floors in the facility, and noted the fresh painting of walls and ceilings.
- 38. The inspection team reviewed the systems used to monitor airflow and pressure gradients in the MCL (Maximum Containment Laboratory; BSL-4). These systems are located in the control room where their operations are reviewed by regular staff logging in prior to entering the MCL. The inspection team believes that it would be a further convenience for these staff, if additional systems (e.g. magnehelic gauges) were to be installed at the MCL entry points during the course of regular maintenance and upgrading. This would provide staff with an immediate opportunity to confirm the pressure differentials.

### **Equipment and maintenance**

- 39. The inspection team examined the animal facilities within the MCL. These facilities can permit some flow of air between different housing areas and thus create a potential for cross-contamination of experimental animals. To minimize the risk of unexpectedly altering the distribution of infection, the inspection team recommend that all animals be further contained within High Efficiency Particulate Air (HEPA) filtered (or equivalently filtered) isolation cages. These cages should also be used to transport animals between procedure and holding rooms and thus prevent any direct exposure of laboratories, corridors and personnel within the maximum containment facility to materials shed by infected animals. The inspection team also recommended that these methods be extended to the necropsy suite, where any manipulations must be performed within a containment device (e.g. a Class II biosafety cabinet) designed to minimize the spread of materials from infected animals into the surrounding laboratory areas.
- 40. The new site of the planned repository was inspected by the inspection team. The facility is well designed and well suited for the proposed purpose. The inspection team recommends that VECTOR review the environmental specifications provided by the freezer manufacturer, with regards to room temperature, and compare them with those observed when all the freezers are operating. Keeping the repository as cool as possible will ensure the optimal performance of the freezers and minimize how often people must enter to repair the compressors.
- 41. The previous recommendations related to filter scan testing and filter decontamination have been adequately addressed.

42. The inspection team did not have much opportunity to inspect the equipment used within the Maximum Containment facility as most of this is currently stored off-site. The engineering team is commended for the manner in which the autoclaves are subjected to regular testing, a practice that ensures the safety of the pressure vessels and that the autoclaves achieve set operating temperatures and pressures. The team recommends that, when spore strips are used to test sterilization efficiency, these strips should be placed within mock (i.e. simulated) loads in order to better reflect real operating conditions.

#### Decontamination, disinfection and sterilization

43. Areas of good practice were identified. The inspection team was advised of two methods approved for use as variola decontaminating agents including fresh 3% solutions of chloramine used in the isolation hospital. At the inspection team's request, an orthopoxvirus killing curve was provided for inspection, the data demonstrated the effectiveness of the protocol. The inspection team asks that a brief description of the method be provided to WHO.

### **Transport procedures**

44. Based upon the Russian Federation's current sanitary rules, VECTOR has developed a procedure for the packaging and transporting of variola virus. There are two protocols, one for transporting live virus and the second for the transport of variola viral DNA. The inspection team proposed that WHO should request that copies of the two protocols be provided by VECTOR's governing agency, Rospotrebnadzor. The WHO inspection team was informed about the procedures that would be used for the safe and secure transport of the repository collection from its current location to its new, permanent location. The WHO inspection team was also assured that the protocol for transporting variola virus will be used for the transport between the new repository and the BSL4 laboratory.

## Security

- 45. The WHO inspection team confirmed that the Maximum Containment BSL-4 research laboratory is secure.
- 46. The corridors and work spaces in the high-containment laboratories are covered by closed-circuit television cameras and images are monitored in a central control unit. Data are recorded digitally and archived in different sites.
- 47. The inspection team recommends that VECTOR transfer highly concentrated stocks of genomic DNA (any solution containing >0.5 µg total purified variola virus DNA) to the repository storage location that is used for the live variola virus. The current method for storing DNA clones, as well as the samples of genomic DNA diluted for PCR purposes, is satisfactory.
- 48. It would be helpful if VECTOR could share its security risk assessment methodology with the WHO inspection team in the course of the next inspection visit. The WHO recommends that VECTOR introduces an overall biosecurity.

#### Variola virus research

49. VECTOR currently has several research projects expected to begin shortly. These fall into three areas approved for work: vaccine, drug and diagnostic development. The projects covered the development of experimental smallpox models for the study of efficacy of anti-smallpox vaccines and drugs, the use of live variola virus for selection of the most effective disinfectants, the maintenance of the Russian national collection of variola virus strains, and the use of live variola virus to provide the development of low-reactogenic vaccines. VECTOR submits proposals first to its governing authorities and then, after obtaining approvals, to the WHO Advisory Committee on Variola Virus Research. The Principal Investigator of the variola virus research programme responds to feedback. Risk assessment is covered by the governance rules of the Maximum Containment Laboratory and health and safety manuals. The research work is currently limited because research proposals have been submitted only recently and await a response from the WHO Advisory Committee on Variola Virus Research. The WHO team noted no concerns about the programme of work and research programme.

#### **CONCLUSIONS**

- 50. The WHO inspection team was impressed by the dedication and the competence of the workforces at the VECTOR site, and was pleased to note that previous recommendations on procedures, safety and facility operation and maintenance had been addressed.
- 51. The WHO inspection team was satisfied with the security and safety arrangements for maintaining, and working with, live variola viruses within the Maximum Containment BSL-4 Laboratory and its associated facilities. The VECTOR's BSL-4 facility was assessed to have the capacity for work to be conducted safely with live variola virus as it stands. However before VECTOR conducts animal experiments, the animal facilities should be inspected by WHO appointed inspectors before any animal work commences. Although a number of recommendations have been made, the WHO inspection team found that VECTOR implements appropriate levels of biosafety and biosecurity for its work with variola virus.
- 52. A positive finding was the recognition by VECTOR staff of the need for continuous improvement and ongoing vigilance. The WHO inspection team recommends the establishment of a continuing collaboration between VECTOR and the other WHO collaborating centre on Orthopoxvirus research located at CDC. Consideration of the recommendations made and confirmation of steps to implement them will contribute to the policy and the process of constant improvement of global biosafety and biosecurity.
- 53. The WHO inspection team found the current version of the assessment protocol to be a useful methodological tool for standardizing the WHO biosafety inspections of the variola virus repositories. The inspection team proposed to use the protocol as a methodological framework for the development of a working tool to facilitate conducting such inspections in the future. At the same time, this assessment protocol should be

harmonized with current national requirements of the Russian Federation regarding the biosafety of the population.

54. This inspection report places no responsibility on WHO for the safe and secure conduct of work at VECTOR with live variola viruses, which remains the responsibility of the research and support staff at VECTOR. The recommendations made above are intended to strengthen the current arrangements for the safe and secure conduct of work on variola viruses.

#### RECOMMENDATIONS

- 55. The WHO inspection team recommends that:
- VECTOR staff collaborate with CDC staff and WHO experts in order to establish a tool based on the CWA 15793 Biorisk Management Standard for future WHO biosafety inspections of the two repositories;
- consideration be given to the further development of the system for recording and learning from all accidents (where these occur) in order that trends can be identified, lessons learned and appropriate preventive action taken;
- all animals be contained in HEPA-filtered (or equivalently filtered) isolation cages and that these cages should also be used to transport animals between procedure and holding rooms, and, further, these methods be extended to the necropsy suite, where any manipulations must be performed within a containment device (e.g. a Class II biosafety cabinet) designed to minimize the spread of materials from infected animals into the surrounding laboratory areas; before VECTOR conducts animal experiments, the animal facilities should be inspected and approved by WHO-appointed inspectors;
- in order to minimize the spread of materials from infected animals into the surrounding animal facilities and maximum containment laboratory, the WHO inspection team recommends a number of practices, including that henceforth all animals be confined and transported in HEPA-filtered (or equivalently filtered) isolation cages, and that before VECTOR conducts animal experiments the animal facilities should be inspected by WHO-appointed inspectors;
- VECTOR staff review the specifications provided by the manufacturer of the freezers in the new repository for variola virus, with regards to room temperature requirement, and compare them with those observed when all the freezers are operating;
- when spore strips are used to test sterilization efficiency of autoclaves, these strips should be placed within mock (i.e. simulated) loads in order to better reflect real operating conditions;

- all samples or materials from individuals infected or suspected of being infected with variola virus must be sent to the Maximum Containment Laboratory in VECTOR;
- given the confirmation that any diagnostic handling associated with smallpox patients is currently handled in the Maximum Containment Laboratory, this practice should be continued; a statement should be provided to WHO stating that diagnostic results provided by the VECTOR Maximum Containment Laboratory will be recognized as being accredited and that confirmatory identification is legally acceptable to the Russian public health authorities;
- highly concentrated stocks of genomic DNA (any solution containing >0.5 µg total purified variola virus DNA) be transferred to the repository storage location that is used for the live variola virus:
- the establishment of a continuing collaboration between VECTOR and the other WHO collaborating centre located at CDC;
- consideration be given at the highest levels to providing the inspection team in advance of its visit with a translation of the latest extant version of the Explanatory Letter:
- for future inspections each WHO inspection team include a qualified technical officer with appropriate language skills in order to facilitate the examination of the documentation provided in each centre.

## **ACKNOWLEDGEMENTS**

The WHO inspection team was grateful to the Director-General of VECTOR and his staff for their cooperation, patience and hospitality during this inspection. The team also appreciates the attendance of the senior staff of the Medical and Sanitary Unit 163, the Territorial Branch of Regional Office 25 of the Federal Medical and Biological Agency, and a representative of the governing authority, Rospotrebnadzor. All staff involved were extremely cooperative and the team was impressed by their motivation and commitment. It was also noted with great satisfaction that high-level management staff members were present during the entire inspection.