World Health Organization

WHO/POLIO/DRAFT/19 February 2020
ENGLISH ONLY

Guidelines for the safe production and quality control of poliomyelitis vaccine

Amendments (2020) to Annex 4 of WHO Technical Report Series, No. 1016

NOTE:

This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Committee on Biological Standardization (ECBS). Publication of this early draft is to provide information about the proposed amendments on WHO *Guidelines for the safe production and quality control of poliomyelitis vaccine* to a broad audience and to improve transparency of the consultation process.

The text in its present form does not necessarily represent an agreed formulation of the Expert Committee. Written comments proposing modifications to this text MUST be received **by 3 April 2020** in the Comment Form available separately and should be addressed to the World Health Organization, 1211 Geneva 27, Switzerland, attention: Department of Health Products Policy and Standards. Comments may also be submitted electronically to the Responsible Officer: Dr Hye-Na Kang at email: kangh@who.int.

The outcome of the deliberations of the Expert Committee will be published in the WHO Technical Report Series. The final agreed formulation of the document will be edited to be in conformity with the "WHO style guide, second edition" (KMS/WHP/13.1).

Contents

Introduction

The WHO Expert Committee on Biological Standardization (ECBS) adopted the WHO Guidelines for the safe production and quality control of poliomyelitis vaccines (1) at its 69th meeting in 2018. These guidelines outline the biosafety measures required for poliomyelitis vaccine production and quality control during the final poliovirus containment stage (Phase III) as defined in the third revision of the WHO Global Action Plan (GAPIII) (2). The biosafety-related steps outlined in these guidelines are to be implemented to minimize the risk of accidentally reintroducing poliovirus from a vaccine manufacturing facility into the community after global certification of poliomyelitis eradication. However, the current Guidelines include several strict requirements related to facility design and quality control testing, which were added after the final round of public consultation to align with GAPIII requirements. Since then, polio vaccine manufacturers have requested WHO to revise these specific requirements, so that each manufacturer can implement appropriate facility-specific measures based on risk assessment. Given the urgent need to increase global supply of polio vaccines, the Fourth Meeting of the Containment Advisory Group (CAG), convened on July 15 to 16, 2019, discussed the request from the polio vaccine manufacturers and agreed to revise relevant sections in the current Guidelines to provide much needed flexibility. Following CAG's decision, the ECBS at its meeting in 2019 recommended amending the Guidelines for the safe production and quality control of poliomyelitis vaccines in Annex 4 of WHO TRS No.1016 (1) to bring these Guidelines in alignment with CAG's decisions (3). The amendments provided in the current document comprise:

- modified requirement for shower when exiting the containment facility;
- permitting the use of non-dedicated quality control laboratories;
- permitting the testing of certain samples taken from containment facility outside of containment laboratories.

No attempt was made at this time to review the WHO Guidelines for the safe production and quality control of poliomyelitis vaccines (1) in their entirety and only the above issues have been addressed.

Amendments

Replace entire Section *7.5.6* with the following:

7.5.6 A full-body shower facility should be available within the personnel exit airlock from the containment facility.

The use of a shower upon exit should follow the established procedure supported by the risk assessment and consistent with the policies established by latest versions of GAPIII (2)[1] *and the most recent CAG decision*[2].

Replace entire Section 11.2 with the following:

11.2 The use of non-dedicated quality control laboratories may be permissible when meeting all of the following conditions:

- *The non-dedicated quality control laboratories are located within the containment laboratories;*
- *All non-poliovirus-related activities performed within the non-dedicated containment laboratories and all personnel admitted into the non-dedicated containment laboratories adhere to all applicable containment procedures;*
- *A thorough risk assessment compliant with the requirements set out in element 2 of GAPIII is performed to identify the additional controls that are necessary to mitigate the risks introduced by operating non-dedicated facilities.*

Replace entire Section 11.5 with the following:

11.5 All samples received from the containment production facility should be handled using established procedures to prevent the release of live poliovirus. Procedures used to decontaminate sample containers or packaging materials should be validated and shown to have no impact on sample integrity. The packaging materials should be decontaminated prior to disposal. All samples received from the containment production facilities – with the exception described below in sections 11.5.1 and 11.6 – should be tested in containment laboratories. All test procedures using reagents containing live poliovirus should also be performed within the containment laboratories.

11.5.1 Certain samples (such as those for water and environment monitoring) taken from the containment areas may be tested outside the containment laboratories if a risk assessment concludes that they are unlikely to contain live poliovirus, based on facility design, equipment used (especially closed system) and sampling locations. However, necessary precautions during sample handling, transportation and disposal may be recommended based on the risk assessment.

Authors and acknowledgements

The first draft of this document was prepared by the WHO Drafting Group comprising Ms A. Bonhomme, Public Health Agency of Canada, Canada; Dr K. Chumakov, Food and Drug Administration, USA; Dr H-N. Kang, World Health Organization, Switzerland; Dr J.

[1] See also: http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/
[2] http://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/

Martin, National Institute for Biological Standards and Control, UK; and Dr T. Wu, Health Canada, Canada.

References

1. Guidelines for the safe production and quality control of poliomyelitis vaccines. In: WHO Expert Committee on Biological Standardization: Sixty-nine report. Geneva: World Health Organization; 2018: Annex 4 (WHO Technical Report Series, No. 1016, Annex 4). https://www.who.int/biologicals/vaccines/Annex_4_WHO_TRS_1016_web4.pdf?ua=1
2. WHO Global Action Plan to minimize poliovirus facility-associated risk after type specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use. GAPIII. Geneva: World Health Organization; 2015. http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf
3. WHO Expert Committee on Biological Standardization: sixty-ninth report. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. TBP