**Comments and suggestions from reviewer**

**Title:** **Recommendations to assure the quality, safety and efficacy of live attenuated rotavirus vaccines**

***Proposed revision of Annex 3 of WHO Technical Report Series No. 941***

# (WHO/ROTA/DRAFT3/PC2/JAN 2024)

**Reviewer’s information (Name, position, affiliation, country, and Email):**

*(Table is expandable)*

| **Sections/Page and Line Number** | | **Original Text** | **Comment** | **Suggested Amendment** | **Internal Use Only**  **[blank]** |
| --- | --- | --- | --- | --- | --- |
| **General comments (if you have)** | | | | | |
|  |  | | | |  |
|  |  | | | |  |
| **Introduction** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Purpose and scope** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Terminology** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **General considerations** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Special considerations** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **International reference materials** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Part A.** **Recommendations on** **the manufacturing and control of live attenuated rotavirus vaccines** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Part B. Nonclinical evaluation of rotavirus vaccines** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Part C. Clinical evaluation of rotavirus vaccines** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Part D. Guidelines for national regulatory authorities** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Authors and acknowledgements** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **References** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Appendix 1. Model summary protocol for the manufacturing and control of live attenuated rotavirus vaccines** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Appendix 2. Model NRA/NCL lot release certificate for live attenuated rotavirus vaccines** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |
| **Other comments (if you have)** | | | | | |
|  | |  |  |  |  |
|  | |  |  |  |  |