

**CAG TC1 on showers**  
**25 January 2018**  
**Report**

**Abbreviations:**

BSC	Biological safety Cabinet
CAG	Containment Advisory Group
CAG1	First Meeting of the Containment Advisory Group, 19-20 June 2017
CAG2	Second Meeting of the Containment Advisory Group, 28-30 November 2017
TC1	First Teleconference of the Containment Advisory Group, 25 January 2018
CCS	Containment Certification Scheme to support the Global Action Plan for Poliovirus Containment (GAPIII)
GAPIII	Global Action Plan for Poliovirus Containment
NAC	National authority for containment
PEF	Poliovirus-essential facility
TRS	Technical Report Series

**Participants:**

CAG:	Professor David Heymann (Chair), Dr Jagadish Deshpande, Dr Atef El-Gendy, Dr Vibeke HalkjærKnudsen, Mr Neil Godden, Dr Janice Lo, Dr Mark Pallansch, Dr Åsa Szekely Björndal, Professor Shahina Tabassum and Mr Kenneth Ugwu.
Excused:	Professor George Griffin, Dr Bernard Fanget, Dr Stephen McAdam
WHO:	Jacqueline Fournier-Caruana, Roland Sutter, Nicoletta Previsani, Harpal Singh called in

**Issue 1: The shower**

**Relevant GAPIII section**

Annexes 2 and 3, Subelement 12.3.1 (g):

*Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except for facilities employing fully functional Class III BSCs or similar isolators (in such facilities, showering out is required in the event of an uncontrolled breach of the primary containment equipment).*

**History**Summary of requests to CAG1

Reconsider the need to install showers for use on exiting the containment perimeter, other than in the event of spill or other significant emergency.

CAG1 recommendation

Modify Subelement 12.3.1 (g) of Annexes 2 and 3 to read as follows:

*Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except **for facilities employing closed systems demonstrating validated primary containment. Such systems may include contained lines for use in vaccine production and/or facilities employing fully functional Class III BSCs or similar isolators. For such facilities, showering out is not mandatory, other than** in the event of an uncontrolled breach of the primary containment equipment.*

CAG2 recommendation

The GAPIII requirements in Subelement 12.3.1 (g) of Annexes 2 and 3, as modified at the 1<sup>st</sup> CAG meeting, were not changed.

The CAG assigned a subgroup to the task to review the issue of mandatory showering, consider the information and evidence around the need/benefits of shower-out (including adherence to the precautionary principle to minimize the risk of release of poliovirus post eradication to as close as possible to zero), and evaluate whether or not a robust set of criteria could be developed for use in risk

assessments to justify the omission of routine showering-out. The CAG agreed to discuss this issue by teleconference in January 2018. Results of CAG discussions on this issue and associated CAG recommendations will be reported and published on the web.

### Summary of CAG TC1 discussions and conclusions

- a. The shower working group presented the flowchart 'Should you shower out'.
- b. The flowchart was discussed and suggestions for improvement were collected.
- c. While not providing 'a robust set of criteria for use in risk assessments to justify the omission of routine showering-out', the CAG agreed on the need to obtain more information and convincing evidence from the field to indicate that showering was not an effective or required control. CAG will not develop a robust set of criteria.
- d. The CAG was reminded of the urgency to provide comments on the shower to the TRS working group before the end of January and the fact many facilities are already designing/building showers to meet the requirement.

In conclusion, while the Containment Certification Scheme (CCS) provides flexibility to PEFs and NACs in terms of installing/using showers until the declaration of global poliovirus eradication, no additional hard evidence has been provided to support the fact that showers do not constitute a significant barrier (e.g. clear definition of containment perimeter, requirement for full clothing change and use of soap and water as a means of physical removal of potentially infectious materials) to the release of poliovirus from facilities post-eradication, justifying the further modification of the requirement 12.3.1 (g) post-eradication, as revised at CAG1. CAG recommendations to the TRS drafting group will reflect these decisions.

### Recommendations

The CAG recommended to further modify the GAPIII requirement in Subelement 12.3.1(g) of Annexes 2 and 3 modified at the 1<sup>st</sup> CAG meeting, to read as follows (text in colour is the GAPIII wording supported by the CAG; changes are shown in bold):

*Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except for facilities employing closed systems demonstrating validated primary containment. Such systems may include contained lines for use in vaccine production and/or facilities employing fully functional Class III BSCs or similar isolators. For such facilities, showering out is **required as a precautionary measure, in the event of an uncontrolled breach of the primary containment equipment, during the period when further assessment of the effectiveness of showering is being undertaken.***

For other facilities, the requirement for mandatory showering should be left to the discretion of the National Authority, after review of a risk assessment submitted by the PEF. Risk mitigation measures will be proposed by the PEF and approved by the National Authority for the interim period of at least two years during which evidence for-or-against-mandatory showering out will be generated.

The CAG urged the secretariat to commission a study to collect information on the use, effectiveness and risks associated with showering, including in facilities where showering is currently being used. The CAG will undertake further discussion on showers when the secretariat has collected the information necessary to make an evidence-based recommendation, or has shown that it is not feasible to collect such information.

CAG recommendations to the TRS drafting group will reflect these decisions.