SESSION OUTLINE PROPOSAL

SESSION IN SHORT	
Organiser of session	WASH R&D Centre (University of KwaZulu-Natal: Dr Danica Naidoo (DN), Dr. Colleen Edith Archer (CEA), Mr Thabiso Zikalala (TZ) & Ms Megan Sigamoney
Other organisations	None
Title	The process of biological method optimisation, from conceptualisation, development, testing, standardisation and ISO 17025 accreditation – The WRDC Helminth Method as an example for successes, lessons learnt and the way forward.
Summary	There is no golden standard for helminth testing globally. Most laboratories implement the USEPA method for helminth egg recovery, which was developed for wastewater and not solid sludges, and can be time consuming and costly to implement. We therefore proceeded to optimize and build on the existing helminth test method implemented in our laboratory, which we then aimed to standardize, and we would then become accredited for. This workshop thus focuses on health and hygiene related to helminthiasis, as well as delineating the entire process of biological method development, from conceptualization to accreditation, all we have learnt thus far, and how to go about doing so in the future.
Objectives	• To provide background information and knowledge on helminths and the human health impact, and to highlight helminth testing and existing methods that built into the WRDC Helminth Method, with focus on how we went about identifying appropriate methods for comparison. • Detail the laboratory setup for helminth testing – what is needed and what needs to be implemented. • To detail the steps taken for method optimization/development.

	• To provide information on how experimentation was designed to ensure all commonly employed existing methods were included in comparative testing. • Provide knowledge and understanding on what standardization entails – implementation of the method in other laboratories and intra- and interlaboratory testing. • Provide details on obtaining certification – what does it require from the organization, laboratory and clients? • Detailing the accreditation process – we are aiming for ISO 17025 accreditation for the helminth method (as well as for solids testing) – the documentation, shortfalls, lessons, limitations, successes and ways forward.
Type of session	☐ Soft Skills Session ☐ Technical Training Session ☒ Workshop
Rationale	There is no golden standard for helminth testing. Furthermore, most test methods were designed for wastewater samples, and are thus unable to accommodate sludge samples. This led to the development of the PRG Helminth Method by Archer and Hawksworth in 2005, later published in Hawksworth et al. (2010), targeting urine diversion dry toilet (UDDT) sludge samples that generally contain soil. This method was modified by Moodley et al. (2008) for a Water Research Commission report, then by Archer, who used it in a study focusing on isolating eggs from soil samples in baboon foraging sites (Pebsworth et al., 2012). The standard operating procedure (SOP) for the method was continuously modified over the years and employed at the Pollution Research Group (PRG) laboratory at the University of KwaZulu-Natal (we are now the Water Sanitation and Hygiene Research and Development Centre (WASH R&D Centre, abbreviated even further to WRDC) for helminth testing, and it formed the foundation for the project funded by the Water Research Commission (WRC) to optimise a single standard helminth test method for implementation in laboratories worldwide. New sludge treatment and toilet technologies are constantly being developed, where helminth eggs must be spiked into the system to test treatment or inactivation efficacy. The processing and recovery of helminth eggs in faecal sludge should thus be consistent. A highly sensitive, standard helminth isolation and enumeration method is therefore required for application in laboratories globally. The latest version of the PRG Helminth Method, that was being implemented at the time, was then tested rigorously against other existing helminth methods: the USEPA (2003), Bailenger (1996) and Mexican Wastewater Analysis Standard (2006) methods. Each step in these methods were tested, where the respective reagents, chemicals, environmental conditions, and the physical and technical aspects were compared. A final modified method, named the WRDC Helminth Method, was adapted based on the data obtained, and was implemented in our laboratory. We then performed rounds of intra-laboratory testing, where the laboratory technicians were tasked with processing samples accruing to the SOP. We provided training to other organisations and laboratories based on the

	modified method. We then approached the South African National Accreditation System (SANAS) to become accredited for the WRDC Method, as we consider ourselves specialists in, and would be the only group in Africa accredited for helminth testing, particularly for a more robust method that could accommodate thicker sludges. We also engaged in inter-laboratory testing of samples with two other laboratories for accreditation purposes. We are currently amidst the accreditation process, and have learnt many lessons thus far. This workshop will be to detail the entire process, from method conceptualisation and development, to modification following rigorous testing, and then comparative intra- and interlaboratory testing, and the entire accreditation process – successes, lessons, shortfalls and the way forward. It will be applicable to helminth testing specifically and the evolution of the project(s), but also method conceptualisation, development/adaptation and accreditation in general, and how to go about this for a laboratory or organisation. This workshop will be as interactive as possible, despite being technical. It can be applicable to laboratory and support staff, researchers and industry personnel interested in method development, laboratory accreditation for methods and helminth testing, and research in general.
Outcome	• Understanding of health and hygiene in WASH with particular focus on helminths and helminth testing – where we came from and where we are now. • Understanding of the method development process - what is required and what goes into planning etc… • Knowledge on the entire standardization process for new methods and existing methods, and intra- and interlaboratory testing. • Understanding certification, accreditation and the entire process – requirements, documentation, challenges and how to proceed.
How to reach the outcome	• Brief introductory talk and discussion around existing test methods. • Question, answer and group discussion session on method development: how would each group go about designing the project from conceptualization to testing. • Presentation and discussion explaining round-robin testing, how to implement a new method in other laboratories, and how to get the method recognized etc… • Discussion session on accreditation – get the audience understanding on certification and accreditation, and their experience with accreditation, specifically ISO 17025.
Tentative Schedule	1) Introductory talk and background on health & hygiene, specifically helminths and helminth testing, focusing on other existing methods and the WRDC Method– 10 minutes – **DN & CEA** 2) Method development: conceptualization, project design, experimental setup, knowledge dissemination. Brainstorm session for each group to discuss – 15 minutes - **DN, CEA, TZ & MS** 3) Interactive session about standardization of a method: round-robin testing, method verification and result validation processes - what would each group do, how would they design processes for method validation and result verification – **DN, CEA, TZ & MS**

	• Discussion between members of each group – 15 minutes • Presentation of each group's discussions – 15 minutes • Discussion of what was actually done and comparison thereof – 15 minutes 4) Discussion of the accreditation process for ISO 17025, interspersed with questions & answers – 20 minutes - **DN, CEA, TZ & MS**
Target Audience	Researchers interested in helminth work, researchers interested in method development, laboratory personnel, policy makers, personnel interested in the accreditation process.
Estimated Number of Participants	50
Proposed Facilitation Method	Presentations, question & answer sessions, discussion sessions
Structure	Speakers, panel discussion, roundtables
Preferred Room Layout	☐ Theater Style ☒ Roundtables ☐ Other Please specify Please note that there is no guarantee from the IWA secretariat that this will be implemented but it will be taken into serious consideration while developing the Congress Programme