General Q&A

Q1. We are writing to kindly request a 2 week extension.

A1. At this time Canada does not anticipate extending the solicitation period for this Call for Proposals.

Q2. Is it possible to discuss with Canada about our technology and the process for applying? **A2**. As we are currently in a solicitation process we cannot speak with Bidders. We invite you to review the two solicitation documents published on BuyandSell.gc.ca listed below. Determine under which call for proposals you are eligible and apply for one call only.

ISC Testing Stream Call for Proposals EN578-21ISC1 and

ISC Testing Stream Call for Proposals EN578-21ISC2

Both Calls, explain how and where to submit your proposal at Part 3 Proposal Preparation and Submission Instructions.

Q3. Will additional ISC Calls for Proposals be published soon?A3. Yes, Innovative Solutions Canada plans to publish at least 1 Call for Proposals per year. Please subscribe to the ISC newsletter for updates on future opportunities.

Q4. Where should proposals be submitted for each Call for Proposal's?

A4. Bidders will be required to create their ISC account in order to submit their proposals in response to both Calls for Proposals. There are two options for creating your account: 1) By clicking the "Submit you Proposal" link in Part 3, Article 3.1.2 of the solicitation documents. 2) By clicking "Submit your Proposal" at Step 5 on the ISC Testing Stream Website <u>here</u>.

Once at the Secure Login Provider page, Bidders can choose either of the two methods for creating their account.

Alternative format to submit

Q5. Can Canada provide a PDF or Word document of the response template?

A5. At this time there is no alternate format for submitting a proposal. The only available option is to complete your proposal using the Electronic Proposal Submission form. Canada will not be evaluating any additional information than what is currently included in the Electronic Proposal Submission form.

Q6. Is there a PDF fillable form to complete a proposal outside of the system?

A6. The Testing Stream Calls for Proposals do not have a PDF Fillable form. Bidders must submit their proposal using the Testing Stream Electronic Proposal Submission Form. The form can be found by clicking the "Submit your Proposal" button at Part 3 Article 3.1.2 of the Calls for Proposals published on BuyandSell.gc.ca. This link will take you to the Secure Login page on the ISC Website where you will be required to login to access the Electronic Proposal Submission form.

Q7. I am interested in learning what products or services the government needs?A7. Part 1 of both Calls for Proposals EN578-21ISC1 and EN578-21ISC2 published on BuyandSell.gc.ca contain a link to the ISC Website Priority Areas. Click on the hyperlink at the end of the following

sentence to consult the details of the Priority Areas on the ISC Website: "Specific information on Priority Areas can be found <u>here</u>."

Difference between EN578-21ISC1 & EN578-21ISC2

Q8. How do I determine to which Call for Proposals to apply?A8. The onus is on Bidders to determine to which Call for Proposals they are eligible to apply.Consult Part 1 Who Can Submit a Proposal of each Call for Proposals to determine your eligibility.

Q9. What are the differences between the two Calls for Proposals EN578-21ISC1 and EN578-21ISC2? **A9**. Call for Proposals EN578-21ISC1 targets eligible Canadian small businesses and Call for Proposals EN578-21ISC2 is open to eligible Canadian businesses and entities who are large companies, non-profit, universities, etc.

Q10. The requirements for participation indicate that a company has to be less than 499 employees. How can larger companies apply?

A10. Two distinct Calls for Proposals were published on BuyandSell.gc.ca. The onus is on the Bidders to determine to which Call for Proposals they are eligible by reviewing Part 1 "Who Can submit a Proposal" of each solicitation document.

Q11. What is the maximum funding for Call for Proposals EN578-21ISC2? **A11**. The correct maximum funding available for Call for Proposals EN578-21ISC2 is \$3M. An amendment will be released shortly to correct reference to the Call number.

Technology Readiness Level Related Questions

Q12. Where can I find more information on the Technology Readiness Levels? **A12**. The Technology Readiness Level (TRL) scale is broken down on the ISC Website <u>here</u>. Innovations under the Testing Stream must be within TRL 7 and 9.

Q13. We are currently in TRL level-5. Please advise if there is an IDEaS or other programs which I could apply for funding support.

A13. Innovative Solution Canada is a program sponsored by ISED Canada. Opportunities are multiple. Our current Testing Stream Call for Proposals EN578-21ISC1 & EN578-21ISC2 are for innovations within TRL 7 to 9.

Q14. We are wondering if we can apply. We have concerns regarding the definition of field testing of a prototype when the technology is a drug. As you may know, the pre-commercial phase for a drug in development is quite long and takes usually close to 10 years. Moreover, in the drug industry, a TRL 7 corresponds to a drug in Phase III of clinical trials, which is not really a prototype at this stage since the drug is tested on populations of thousands individuals with a study cost of 20M+ in average.

We were wondering if this definition is what you consider field testing of a prototype when the technology is a drug? We would really appreciate if you could help us understand if, and how, the "Testing Stream" program can help as synthetic biology company in the therapeutic industry, which falls under the "Health/Bio and nanotechnologies" category.

A14. It is imperative that the proposed innovation be at a minimum at TRL 7: Prototype system ready (form, fit and function) for demonstration in an appropriate operational environment. At the time of bid submission, the Bidder must demonstrate that they have obtained all the certifications, licences and approvals required to safely deploy the proposed innovation in an operational setting and that remaining certifications yet to be obtained for the commercialization of the proposed innovation do not pose safety concerns for the Government of Canada organizations when used in an operational setting. This is to ensure that the potential Government of Canada organization testing the prototype is not exposed to safety issues or risks during the conduct of the tests.

Q15. In relation to Technical Criteria SC3 Deployment Readiness and Safety Considerations, can Canada identify which certifications, licences, and approvals are required for a given innovation?

A15. The onus is on Bidders to determine the certifications, licences, and approvals required for their type of innovation.

Bidders must demonstrate, at time of proposal submission, that they have obtained all the certifications, licences and approvals required to safely deploy the proposed innovation in an operational setting and that remaining certifications yet to be obtained for the commercialization of the proposed innovation do not pose safety concerns for the Government of Canada organizations when used and tested in an operational setting. This is to ensure that the potential Government of Canada organization testing the prototype is not exposed to safety issues or risks during the conduct of the tests.

Eligibility related questions

Q16. Is it possible to relax the 80% Canadian Content mandatory criteria?

A16. At this time the Testing Stream is not considering reducing the Canadian Content Requirement therefore Bidders must ensure innovations demonstrate 80% Canadian Content in accordance with article 1.5 Canadian Content A3050T (2020-07-01) Canadian Content Definition of the solicitation document in order to be considered for this requirement.

Q17. Would a currently commercialized technology be eligible under the Testing Stream if we add new features?

A17. The onus is on Bidders to determine if they are eligible to apply to a Call for Proposals. Bidders should consult Appendix 1 Evaluation Grid, MC5 and Appendix 2 Definitions of Pre-Commercial Innovation and Commercial Sales as well as SC1 Innovation with respect to its definition of Innovation (i.e. significant modifications to the application of existing technologies/components/processes)

Q18. If the CEO of my company, who does not have a controlling interest and/or ownership of my company but also happens to be the CEO of another company who also does not have a controlling interest and/or ownership of my company then would this mean that we are classified as an affiliate?

A18. If you are able to prove that your company is not the parent or holding company of the other business and that the other business is not partially or wholly owned by your company then you would not be classified as an affiliate. Note that should you prequalify under Call for Proposals

EN578-21ISC1, the Small Business certification will be thoroughly re-validated prior to award of any resulting contract.

Q19. Can we resubmit a pre-qualified application or should we introduce a new application? **A19**. As stated in the published Calls for Proposals, at Appendix 1, MC6 Previously Pre-qualified Innovation, "The proposed innovation or any other versions of the proposed innovation must not have been previously awarded a contract in the Build in Canada Innovation Program (BCIP) or its predecessor, the Canadian Innovation Commercialization Program (CICP), nor under any Innovative Solutions Canada (ISC) Streams. The proposed innovation or any other versions of the proposed innovation must not currently be active in a pool of pre-qualified innovations in any of the above. A proposed innovation that is currently active in a pool will be accepted only once the bid validity period for that proposal has expired or the Bidder has withdrawn their innovation from the relevant pool in collaboration with the Contracting Authority. A Bidder can participate more than once, as long as the proposed innovations are sufficiently different. All applications submitted under this CFP will be evaluated on its own merits and against its criteria. Pre-qualifying under a previous CFP does not guarantee a pre-qualification under this CFP.

MC5: Pre-commercial status

Q20. We have a question about pre-commercialization. We have been developing a proof-of-concept solution. To date we have developed four different prototypes and they have deployed these solutions in the real world environment, each prototype has been iterated on based on feedback. No final product has been approved and the product has not been commercialized outside the projects. However, the company has paid for each iteration of the prototype to cover costs. Does this make us ineligible for applying for the testing stream?

A20. As outlined in Appendix 1 – Evaluation Grid, Mandatory Criteria MC5 of the Call for Proposals, the proposed innovation must not be openly available in the marketplace, and must not have been previously sold on a "commercial basis" as of the date of this bid submission. Please refer to the definitions of Pre-Commercial Innovation and Commercial Sales at Appendix 2 – Definitions, of the solicitation documents.

Q21. Our innovation in healthcare is at the point where it is ready to be tested in clinical trials. Would this be an eligible cost?

A21. The onus is on Bidders to determine what the eligible costs for their innovation are. We invite you to read the entire Call for Proposal and the section 3.4 Financial Proposal and online Electronic Proposal Submission form, Section H – FINANCIAL PROPOSAL.

Other

Q22. We are wondering if hospitals in Canada are considered "government" or "federal organization" per the Testing Stream call for proposals. Our device would need to be tested in a hospital.

A22. ISC stipulates that "any Government of Canada organization (including Crown Corporations) can test innovations. Provinces, municipalities, hospitals, schools, and Indigenous organizations may also be testing partners (with a federal sponsor). ISC will be responsible to find a federal government organization to sponsor the test." Reference: https://www.ic.gc.ca/eic/site/101.nsf/eng/00105.html