AAMI New Work Item Proposal (NWIP) Form Instructions

Please review existing committee or working group scopes prior to submitting a new work item proposal to ensure that the most relevant group of experts provides feedback on the proposed content.

- ✓ Where a committee or working group already exists, AAMI circulates new work item proposals to the full committee for review and comment.

- ✓ If the proposal does not fall within the scope of an existing committee, AAMI will conduct an additional evaluation to determine if the formation of a new committee or working group is necessary.

- ✓ If no significant objections are received from committee or work group members regarding the proposal, the NWIP and any supporting documentation are forwarded to the AAMI Standards Board for review and consideration for approval.

- ✓ The Standards Board will consider several factors, including:

    - o whether the work supports AAMI's Strategic Plan;

    - o the criticality of the gap or need that the project intends to address;

    - o the feasibility of completing the work in a timely manner;

    - o whether AAMI has sufficient resources, including stakeholder participation, to undertake the new work.

- ✓ If the project is approved, AAMI will notify both the committee and proposed project leader as soon as possible.

Tips on filling out the form:

- ⸺ Item 1, Project title: The proposed title should accurately reflect the proposed content while being as concise as possible.

- ⸺ Item 2, Scope: The scope should be written in such a way that it defines without ambiguity the subject of the document and aspects covered.

- ⸺ Item 5, Gap statement: Explain what the technical gap is that exists with current standards or guidance documents and how this project intends to fill that gap.

- ⸺ Item 6, Strategic plan relevance: Provide specific information regarding how this proposed project will support the AAMI strategic plan.

- ⸺ Item 7, Existing work: Please investigate whether there are any standards or other guidance documents/projects that have been developed or are currently in development in other organizations (domestic or international) that may either relate, affect, or duplicate (either partially or entirely) the proposed work and provide that information.

- ⸺ Item 9, Reference or background materials: Please list any articles, published papers, or data sources that might be used as references for this project.

- ⸺ Item 16, Expected project development: Please indicate if it is anticipated that the project might take longer than the two to three-year development time, e.g. to accommodate new test method verification and validation activities, to achieve consensus on a contentious issue, etc.

SECTION A: Project Information

1. **Proposed project title:** Click or tap here to enter text.

2. **Scope** *(describes what the document does (e.g. "specifies", "establishes", "gives guidelines for", "defines terms", etc.); worded as a series of statements of fact; and does not contain requirements, recommendations, or permissions)*:

   Click or tap here to enter text.

3. **Please indicate project type** (select only one):

   ☐ Standard

   ☐ Technical Information Report

   ☐ Provisional Standard

   ☐ Amendment to published standard or TIR

   ☐ Other (please specify Click or tap here to enter text.

4. **Proposed project contact name and email address:**

   Click or tap here to enter text.

SECTION B: Market/Stakeholder Relevance

5. **Please describe the specific gap or need that the proposed project is going to fill:**

   Click or tap here to enter text.

6. **Please describe the relevance of this proposed project to AAMI's Strategic Plan:**

   Click or tap here to enter text.

7. **Does this work relate to, affect, or possibly duplicate existing standards or work within AAMI or other organizations?** *(e.g. ISO, IEC, ASTM, etc.)*

   ☐ Yes

   Please list those documents or projects here: Click or tap here to enter text.

   ☐ No

8. **Please indicate if a published document, outline, table of contents, or other information will serve as the basis of this proposed document:**

   Click or tap here to enter text.

9. **Please list any reference(s) and/or other background materials to support this proposal:**

   Click or tap here to enter text.

10. **Are there any known patent issues?**

    ☐ No

    ☐ Yes. Please describe: Click or tap here to enter text.

11. **Who is the intended audience?** *(select all that apply)*

    ☐ Industry/Manufacturing   ☐ Regulatory Bodies   ☐ Testing/Labs   ☐ HTM Professionals

    ☐ Academia   ☐ Outside U.S.   ☐ Consumers

    ☐ Healthcare Delivery Organization Clinical Users   ☐ Other *(Please specify):* Click or tap here to enter text.

SECTION C: Consensus Body Considerations

12. **Please review the list of current [AAMI Committees](). Is there an existing AAMI committee/working group that this project should be assigned to?**

    ☐ Yes

    Please specify committee/working group: Click or tap here to enter text.

    ☐ No

13. **Please list any other AAMI committees/work groups that might provide appropriate input on the project.**
    (e.g., the Medical Device Alarms Committee if a device standard contains requirements regarding alarm signals).

    Click or tap here to enter text.

14. **Please select all stakeholders that will contribute/participate in this project:**

    ☐ Industry

    ☐ Users

    ☐ Regulators

    ☐ Other

15. **Does the project need participation and/or input from other professional or trade associations, clinical user groups, academia, etc.?**

    ☐ Yes

    Please list organizations and/or individuals (including contact information): Click or tap here to enter text.

    ☐ No, the group has the expertise and stakeholder input balance needed.

16. **Do you foresee any potential extenuating circumstances that might prolong the standards development process/timeline** (e.g. additional time for verification and validation activities for a new test method) **or require additional resources from AAMI** (e.g. legal review)**?**

    ☐ Yes

    Please specify nature of extenuating circumstance, estimated length of delay (several months/years) and additional resources (if anticipated): Click or tap here to enter text.

    ☐ No