

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION
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Annex B -- New Work Item Proposal

Return to AAMI Attention: standards@aami.org

1. Project Title

2. Project Type (e.g., standard, recommended practice, technical information report, monograph, other [describe])

3. Scope of the Project

Please describe the technical subject of the standard, recommended practice, technical information report, or other project. For documents, provide a draft scope statement. (Attach an additional sheet, if necessary.)

4. Need

Please describe in detail the clinical/healthcare needs to be addressed, providing, if applicable, copies of relevant literature. If the proposed project is the development of a medical device standard, identify the risks to patient health to be addressed and give the FDA classification of the device. (SEE ALSO part 4a).

4a) International relevance

Please identify any international standards (in progress, or final) that relate to the proposed scope of the project. If any international standards exist or are under development, explain why a U.S. standard or recommended practice is needed, versus adopting the international standard as a U.S. standard or recommended practice. [NOTE: All AAMI technical committees undertaking new work should review any relevant international standards of the ISO or IEC when first beginning the project and throughout its development. The committee should discuss at the outset the possibility of: formally adopting the international standard as a U.S. standard; or deferring any work on a U.S. standard (that is, adopting the international standard as a "de facto" U.S. standard). If neither of these are acceptable to the committee, or there are no international standards (final or in progress), and work proceeds to develop a U.S. standard under AAMI auspices, the AAMI committee should remain current on relevant international standards developments (if any) and, to the extent possible, harmonize its document with any international standards. Committees that have completed U.S. standards or recommended practices for which there is a corresponding international standard (final or draft) will be asked to provide a report, updated as necessary, describing areas of harmonization, and areas of difference between the U.S. and international documents.]

5. Vehicle

Please explain why the standard, recommended practice, technical information report, or other vehicle is the best approach to addressing the clinical/health care needs described in part 4. For example, why a standard rather than a recommended practice or technical information report?

6. Why AAMI?

Please explain why AAMI is the appropriate organization to undertake the project. Identify any other organizations that could reasonably be expected to have an interest in the proposed project and/or that already have relevant work in progress.

9a) Request for extended schedule of completion (consensus documents only)

(Co)chairs, on behalf of a committee, may "negotiate" an extended schedule with the Standards Board by providing a written request c/o the AAMI Vice President of Standards Policy and Programs explaining why an exception is necessary, and how much additional time is needed. If the above schedule is not within the specified maximum period allowed for completion, please provide a detailed explanation of why additional time is needed.

10. Financial Resources

Please describe any extraordinary resources that will likely be needed for the proposed project and how these resources can be obtained; for example, if a user travel fund is planned, explain how it will be established and maintained. Also identify any potential sources of funding, such as government grants, corporate contributions, and the like.

11. Person(s) to Contact for Further Information

11a. Submitted by (Please provide your name, address, phone number and email address here)

11b. On behalf of (Please indicate the company, committee, association, etc. that has officially asked you to submit this proposal on their behalf, if applicable. If not applicable, leave blank or indicate "self.")

11c. Other persons to contact for further information. If applicable, please provide the names, addresses, phone numbers and email addresses of other individuals who can be contacted about the proposed project should AAMI staff or the Standards Board have questions or need additional data.

For Office Use Only	
Date Received	_____
Date to SB	_____
Action Taken	_____
If Approved, Scheduled Completion Date:	