ISSC 2023
Committee Report

Committee Name: Laboratory Committee
Committee Chair: Andy Haines
Meeting Dates: Multiple Conference Calls 2020-2023

Committee Members:

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Joseph DeCrescenzo
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Jessica Jones (FDA Advisor)
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Sara McGrath (FDA Advisor)
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Charges

Charge 1: Proposal 13-111: DSP PPIA Kit for Determination of Okadaic Acid Toxins Group (OA, DTX1, DTX2) in Molluscan Shellfish

Findings/Conclusions: A partial data package was provided by the submitter in June 2017 and reviewed at the 2017 Biennial Meeting. After additional review, the Laboratory Committee provided feedback on this submission in June 2018. No further data has been received from the submitter since that time, and a letter from the Lab Committee and Executive Office sent on 9/23/2020 inquiring on the submitter's intent to continue pursuing this proposal went unanswered.

Recommendation: ISSC Constitution, Bylaws, and Procedures – Procedure XV, Section 7, Subdivision A, states that "the method submitter has eighteen months from the date of the written request from the ISSC to provide the information/data necessary to complete the evaluation of the method. If there is no

response from the submitter within this timeframe, the Laboratory Committee will recommend no action on the Proposal." In accordance with this Procedure, in November 2020 the Laboratory Committee voted to recommend that Task Force 1 take no action on this proposal.

Charge 2: Proposal 13-114: Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination

Findings/Conclusions: At the 2013 Biennial Meeting, this method was approved for use with mussels, and was approved for limited use with clams and scallops for the purposes of screening and precautionary closures. At the same time, this method was referred back to committee for further study for use with oysters, and since that time, all of the subsequent data submissions and Laboratory Committee reviews associated with this proposal have been focused on assessing the method's suitability for use with oysters. Most recently, the Laboratory Committee met with the proposal submitters in February 2021, and then provided a detailed feedback letter to them in April 2021. It was determined in March 2023 that the original submitter of the oyster data is no longer able to continue pursuing this proposal. Although there is still interest for this method approval within the program, another entity has not yet been identified to take up this work, and it is likely that they would take it up as a matrix extension instead of a full validation.

Recommendation: The Laboratory Committee recommends that Task Force 1 take no action on this proposal.

Charge 3: Proposal 15-109: PSP HPLC-PCOX Species Expansion

Findings/Conclusions: This method has been approved for use with mussels, soft-shelled clams, oysters, and scallops. This proposal aims to expand the approval of this method for use with geoducks and clams. Most recently, the Laboratory Committee received an updated data package in support of this proposal in September 2020, and sent a detailed feedback letter to the submitter in January 2021. In February 2023, it was confirmed with the submitter that, while they still intend to pursue the proposal, they will not have an updated data package ready in time for the biennial meeting.

Recommendation: The Laboratory Committee recommends that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 4: Proposal 15-112: Direct Plating Method for trh

Findings/Conclusions: In July 2021, the method submitter indicated to the Laboratory Committee that a key component for this method, the DNA probe, was no longer being manufactured. The submitter intends to redevelop the method using new and readily available components, and will resubmit as a new proposal once this work is complete.

Recommendation: Because the DNA probe necessary for this method is no longer available, the Laboratory Committee voted in October 2021 to recommend that Task Force 1 take no action on this proposal.

Charge 5: Proposal 15-114: Male-Specific Coliphage Enumeration in Wastewater by Direct Double-Agar Overlay Method

Findings/Conclusions: This proposal seeks to introduce a new method into the program that will allow for the quantification of MSC in wastewater. Most recently, in July 2021, the Laboratory Committee received an updated data package intended to address questions and concerns from previous LC reviews, as well as suggested method-specific additions to the Microbiology Lab Evaluation Checklist. During the review, the committee determined that the updated dataset adequately addressed all previous comments. The committee also worked with the submitter to finalize the method SOP document, and to update the draft laboratory evaluation checklist to ensure that it matches the method that was submitted.

Recommendation: In order to ensure that the additional data, SOP, supporting documents, and laboratory evaluation checklist edits included in Attachment 1 are included in the permanent ISSC record and Summary of Actions associated with this proposal, the Laboratory Committee recommends that this document be appended to the original proposal.

The Laboratory Committee also recommends that an additional amendment be made to Microbiology Lab Evaluation Checklist Item 1.7.15, so that it reads “The pH of the prepared media is determined after sterilization to ensure that it is consistent with the manufacturer’s requirements, unless otherwise specified in the original method documentation. Results are recorded and records are maintained.”

Finally, Laboratory Committee recommends that Task Force 1 adopt this proposal as amended.

Charge 6: Proposal 17-103: Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Method for the Determination of Diarrhetic Shellfish Poisoning (DSP) Toxins in Shellfish.

Findings/Conclusions: The Laboratory Committee has been in communication with the submitter about the status of this proposal, and they have indicated that they still intend to pursue it, but will not have an updated data package ready in time for the 2023 Biennial Meeting.

Recommendation: In January 2023, the Laboratory Committee voted to recommend that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 7: Proposal 17-106: Matrix Expansion for the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination to Allow Use with Geoduck

Findings/Conclusions: This is another matrix extension proposal for the same method described in Proposal 13-114, except in this case the work has been focused on extending the approval for this method for use with geoducks. The last dataset was sent in by the submitter in November 2018, and the Laboratory Committee is awaiting an updated data package before making a recommendation. The Laboratory Committee has been in communication with the submitter, who has indicated that they still intend to pursue this proposal, but will not have an updated data package ready in time for the 2023 Biennial Meeting. An additional entity has indicated that they will be helping to complete the validation work as well.

Recommendation: The Laboratory Committee recommends that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 8: Proposal 17-108: Detection of ASP biotoxins in *Mytilus edulis* (Blue Mussel) shellfish by ELISA for Domoic Acid

Findings/Conclusions: The submitters provided an updated data package to the Laboratory Committee in September 2021, and shortly thereafter the Laboratory Committee provided them with feedback on additional validation work that needed to be done. In March 2023, the Laboratory Committee received

an updated submission that included a draft lab evaluation checklist, but did not include any additional data or make the modifications necessary to the supporting documents that would address all of the outstanding Laboratory Committee questions and concerns. The Laboratory Committee intends to communicate with the submitter to reiterate the feedback provided in 2021, but was not able to in advance of the Biennial Meeting.

Recommendation: The Laboratory Committee recommends that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 9: Proposal 17-110: Alkaline Phosphatase Probe Method for Vibrio vulnificus and Vibrio parahaemolyticus Detection in Oysters – Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to introduce a laboratory evaluation checklist for the Alkaline Phosphatase Probe Method for Vv and Vp Detection in Oysters. A checklist was originally proposed in 2017, but during initial Laboratory Committee review, several notable concerns arose about how the checklist was originally written. As a result, the submitter completely rewrote the checklist, and resubmitted for the 2019 Biennial Meeting. A full review was not completed at that meeting, so the checklist was referred back to committee. During the current review, the Laboratory Committee made amendments to the 2019 submission in response to concerns from Committee Members who utilize this method with regularity, specifically on page 1 (with reference to Section 3.4) and in Line Item 3.6.1. Additional changes were made to Line Items 1.4.25 and 1.6.3 in order to harmonize with changes to the Microbiology Checklist that were approved at the 2019 Biennial Meeting. This amended checklist was granted interim approval at the 4/2021 Executive Board Meeting, and is appended to this report as Attachment 2.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as amended.

Charge 10: Proposal 19-101: Conditionally Conforming Laboratory Status

Findings/Conclusions: This proposal seeks to create an additional laboratory status of “Conditionally Conforming”, and lays out the requirements that a laboratory would have to meet in order to achieve this status. During discussion, concerns arose about the adequacy of the listed requirements as stand-alone ways of providing sufficient assurance that all aspects of laboratory operations are protective of

public health. However, committee members also expressed an interest in having a mechanism for more rapid "emergency" lab approval for situations like COVID, and the committee would like more time to develop that language.

Recommendation: The Laboratory Committee recommends that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 11: Proposal 19-128: Laboratory Method for *Vibrio parahaemolyticus* and *Vibrio vulnificus* Enumeration and Detection Through MPN and Real-Time PCR

Findings/Conclusions: Most recently, in March 2022, the submitter provided the Laboratory Committee with a proposed study design for the experiments necessary to address previous Committee comments. The Laboratory Committee provided feedback and recommendations on that study design, and the submitters completed an updated data package in January 2023. The Laboratory Committee had a few remaining outstanding questions after reviewing this updated data, and provided that feedback to the submitters. The submitters indicated that they still intend to complete the work, but have to wait until the summer season to be able to acquire the appropriate samples.

Recommendation: The Laboratory Committee recommends that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 12: Proposal 19-131: NSSP Microbiology Laboratory Evaluation Checklist – Reagent Water Quality

Findings/Conclusions: This proposal seeks to modify Line Item 1.7.6 of the Microbiology Laboratory Evaluation Checklist. During review, the Laboratory Committee determined that the proposed modifications would change the requirement for resistivity to a higher standard without changing the directly related conductivity requirement. The changes proposed were also found to be overly specific and limiting to labs, as the language only allowed for mixed bed deionizers, and did not allow for other methods of producing distilled or deionized water. The existing checklist language is consistent with the requirements in "Standard Methods" – Microbiology Examination section, Table 9020: II, Quality of Reagent Water Used in Microbiology Testing, which is commonly referenced in NSSP labs. The Standard Methods errata that was cited in the original proposal was reviewed and it was determined that there was no justification for changing the resistivity value in Line Item 1.7.6.

Recommendation: In May 2022, the Laboratory Committee voted to recommend that Task Force 1 take no action on this proposal.

Charge 13: Proposal 19-132: Microbiology Laboratory Evaluation Checklist – Working Thermometers

Findings/Conclusions: This proposal seeks to modify Line Item 1.4.24 of the Microbiology Laboratory Evaluation Checklist by adding rejection criteria for working thermometers and by improving the language used in this section. The Laboratory Committee review determined that these changes were appropriate and consistent with the Standard Methods reference.

Recommendation: In April 2022, the Laboratory Committee voted to recommend that Task Force 1 adopt this proposal as submitted.

Charge 14: Proposal 19-133: Microbiology & PCR Laboratory Evaluation Checklists – Working Thermometers

Findings/Conclusions: This proposal seeks to modify the working thermometer requirements contained within Line Item 1.4.20 of the Microbiology Laboratory Evaluation Checklist by removing the term "calibrated" from several locations and replacing it with alternate language describing accuracy requirements. During review, the Laboratory Committee determined that maintaining the calibration requirements in this checklist item is important, and that the proposed language would be overly prescriptive and would hold NSSP laboratories to a higher standard than necessary. Amended language was suggested in order to maintain the calibration requirements while still addressing the thermometer accuracy concerns expressed in the original proposal. The amended language is appended to this report as Attachment 3.

Recommendation: In May 2022, the Laboratory Committee voted to recommend that Task Force 1 adopt this proposal as amended.

Charge 15: Proposal 19-136: NSSP DSP Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to introduce a Laboratory Evaluation Checklist for the Liquid Chromatography Tandem Mass Spectrometry Method for the Determination of Diarrhetic Shellfish Poisoning Toxins in Shellfish. This laboratory method was approved by the Conference for use with clams at the 2017 biennial meeting, and is still under review for use with mussels and oysters, but a lab evaluation checklist was not included with the original method proposal.

The Laboratory Committee, as well as invited guests with expertise in this method, provided a detailed review of this proposed Laboratory Evaluation Checklist and made extensive amendments to ensure that this highly technical checklist remained consistent with the original method as approved by the Conference, but was not overly prescriptive. This amended checklist was granted interim approval at the 11/2021 Executive Board Meeting, and is appended to this report as Attachment 4.

Line Item 2.4.5 of the original proposed checklist required that a refrigerated autosampler be used for analysis, as that is the piece of the equipment that was used during original development of this method. During review, however, several method users indicated that they did not have access to a refrigerated autosampler, so would not be able to meet this checklist requirement. In order to address this concern, the method developer ran additional experiments to determine the impact on method performance of using a non-refrigerated autosampler. It was found that a 24-hour holding time at room temperature did not impact test results, so this checklist item was amended to allow for increased flexibility, with certain restrictions. The results and conclusions from these experiments are appended to this report as Attachment 5.

Recommendation: In order to ensure that the additional data included in attachment 5 is included in the permanent ISSC record and Summary of Actions associated with this proposal, the Laboratory Committee recommends that this document be appended to the original proposal.

The Laboratory Committee also recommends that Task Force 1 adopt this proposal as amended.

Charge 16: Proposal 19-138: NSSP Microbiology Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to improve checklist consistency by updating several NSSP requirements in Part 1 of the Microbiology Laboratory Evaluation Checklist to incorporate current NSSP lab practices while still maintaining the original intent of the requirements. The Laboratory Committee review determined that these changes were appropriate as presented.

Recommendation: In July 2022, the Laboratory Committee voted to recommend that Task Force 1 adopt this proposal as submitted.

Charge 17: Proposal 19-140: NSSP Microbiology Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to update the existing Laboratory Evaluation Checklist for the Modified Double Agar Overlay Method for Determining Male Specific Coliphage in Shellfish. This method and the original version of this checklist were approved for use in the program following the 2009 biennial meeting, so Laboratories and Laboratory Evaluators have extensive experience using this method and checklist, which helped to inform most of the changes that were made. This method was originally approved for use with soft-shelled clams and oysters, but has since been approved for use with hard clams as well, so the title of this checklist section has been updated to reflect the broader scope. Other modifications were made in sections 3.10 through 3.15 in order to reduce redundancy and improve organization and clarity, as well as to better reflect best practices for method implementation. The references were also reviewed and updated.

Although the primary intent of this proposal is to update sections 3.10 to 3.15 of the existing Microbiology Checklist, the submitters also used this as an opportunity to modify other sections of the checklist to ensure consistency in the terminology and formatting used throughout. None of the changes included in pages 1 – 14 of this updated checklist modify any existing requirements.

This amended checklist was granted interim approval at the April 2022 Executive Board Meeting, and is appended to this report as Attachment 6.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as amended.

Charge 18: Proposal 19-141: NSSP Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP) Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to introduce a Laboratory Evaluation Checklist for the Receptor Binding Assay for Paralytic Shellfish Poisoning. This method was originally introduced to the program as an alternative to the mouse bioassay for PSP in mussels following the 2013 biennial meeting,

and was also approved for limited use with clams and scallops for the purposes of screening and precautionary closures, but a lab evaluation checklist was never developed.

Amendments to this checklist are the result of a collaboration between Laboratory Committee members and invited guests with expertise in this method. In particular, Items 1.2.5 and 1.2.6 were updated to better reflect the licensing requirements for handling radioactive materials, and Items 2.3.2 and 2.4.5 were updated to reflect best practices. Item 2.4.10 was updated to make this a requirement instead of being optional, as the material used in this step of the method can be variable in quality.

This amended checklist was granted interim approval at the April 2022 Executive Board Meeting, and is appended to this report as Attachment 7.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as amended.

Charge 19: Proposal 19-150: Neogen's 'Reveal 2.0 for PSP' for detection of PSP

Findings/Conclusions: The Laboratory Committee provided feedback on initial data submissions associated with this proposal in 2018 and 2019, and provided the submitter with additional feedback on study design in 2020, and is awaiting a revised data package before making a recommendation. The Laboratory Committee has been in communication with the submitter about the status of this proposal, and they have indicated that they still intend to pursue it, but will not have an updated data package ready in time for the 2023 Biennial Meeting.

Recommendation: In January 2023, the Laboratory Committee voted to recommend that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 20: Proposal 23-105: Request to rescind the Vibrio vulnificus enzyme immunoassay method

Findings/Conclusions: This proposal represents a request to remove the Vv EIA method from the list of approved methods within the program. There are no laboratories using this method, and the antibody necessary to carry out the method is no longer manufactured or sold, so it is impossible for laboratories to implement this method moving forward.

Recommendation: In January 2023, the Laboratory Committee voted to recommend that Task Force 1 adopt this proposal as submitted.

Charge 21: Proposal 23-106: Request to rescind the Vibrio vulnificus SYBR Green real time PCR method

Findings/Conclusions: This proposal represents a request to remove the Vv SYBR Green Real-Time PCR method from the list of approved methods within the program. There are no laboratories using this method, and the equipment necessary to carry out the method is no longer manufactured or supported, so it is impossible for laboratories to implement this method moving forward.

Recommendation: In January 2023, the Laboratory Committee voted to recommend that Task Force 1 adopt this proposal as submitted.

Charge 22: Proposal 23-114: Domoic Acid (Amnesic Shellfish Poisoning) HPLC Method Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to make modifications to the existing Laboratory Evaluation Checklist for the HPLC Method for Domoic Acid (ASP). The Laboratory Committee began review of this proposal prior to the Biennial Meeting, and during discussion, concerns arose about the consistency of some of the proposed changes with how the original method as adopted into the program is carried out. The submitters of this proposal were unable to attend the Biennial Meeting to continue that discussion, and the Laboratory Committee would like additional time to discuss with the submitters to try and address those concerns.

Recommendation: The Laboratory Committee recommends that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 23: Proposal 23-115: Paralytic Shellfish Poisoning (PSP) HPLC-PCOX Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to make modifications to the existing Laboratory Evaluation Checklist for the PSP HPLC-PCOX Method. The Laboratory Committee was not able to begin review of this proposal prior to the Biennial Meeting, but there are similar concerns about the consistency of the proposed changes with how the original method as adopted into the program is carried out. The submitters of this proposal were unable to attend the Biennial Meeting to participate in the discussion, and the Laboratory Committee would like the opportunity to have that conversation with them before making a final determination.

Recommendation: The Laboratory Committee recommends that Task Force 1 refer this proposal to an appropriate committee as determined by the conference chair.

Charge 24: Proposal 23-116: NSSP Microbiology Laboratory Evaluation Checklist – Sample Diluent

Findings/Conclusions: This proposal introduces modifications to the existing Microbiology Laboratory Evaluation Checklist that are intended to reduce the potential for a laboratory to receive multiple non-conformities for the same deficiency. Specifically, checklist items 1.7.14 and 3.2.13 both reference the use of sterile phosphate buffer as the sample diluent. During discussion, it was recognized that there are some references later in the checklist related to alternative diluents, so amended language was added to exclude those items from this checklist line. The amended checklist is appended to this report as Attachment 8.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as amended.

Charge 25: Proposal 23-117: Modifications to NSSP Quality Systems Evaluation Checklist

Findings/Conclusions: This proposal seeks to make updates to the existing NSSP Quality Systems Evaluation Checklist. This checklist has been utilized for a few years, and these changes are intended to provide clarity, standardize language, and combine items to reduce redundancy.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as submitted.

Charge 26: Proposal 23-118: Part 1 Modifications to NSSP Microbiology Laboratory Evaluation Checklist

Findings/Conclusions: This proposal introduces several modifications to Part 1 of the existing Microbiology Laboratory Evaluation Checklist. These changes are all intended to improve the consistency and accuracy of the language used, reduce redundancy, and in some cases increase the options available to laboratories. During discussion, an updated reference for checklist item 1.6.7 was added. The amended checklist is appended to this report as Attachment 9.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as amended.

Charge 27: Proposal 23-119: NSSP Microbiology Laboratory Evaluation Checklist – Productivity Controls

Findings/Conclusions: This proposal seeks to modify the existing Microbiology Laboratory Evaluation Checklist items relating to productivity controls in order to reduce the potential for a laboratory to receive multiple non-conformities for the same deficiency. In the existing checklist, there were multiple sections within the checklist where labs could receive critical deficiencies if they were not using the proper productivity controls. This proposal strikes all of the method specific productivity control checklist items, and combines them into a single checklist item, 1.7.13. During discussion, an updated reference was added for this checklist item. The amended checklist is appended to this report as Attachment 10.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as amended.

Charge 28: Proposal 23-120: Modification of MARBIONC Brevetoxin (Neurotoxic Shellfish Poisoning) ELISA Method Laboratory Evaluation Checklist

Findings/Conclusions: This proposal seeks to introduce modifications to the existing Laboratory Evaluation Checklist for the MARBIONC Brevetoxin ELISA Method. This checklist was utilized for the first time recently, and this proposal introduces some modifications based on that experience to improve clarity and reduce redundancy.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as submitted.

Charge 29: Proposal 23-122: Addition of Vv MPN Real-Time PCR to Microbiology PCR Checklist

Findings/Conclusions: This method was approved for use within the program at the 2019 Biennial Meeting, but necessary checklist modifications were not made at the same time. This proposal seeks to update the PCR checklist by adding in the appropriate primers and probes associated with this method.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as submitted.

Charge 30: Proposal 23-125: Guidance for Laboratory Method Matrix Extensions

Background: The approval of laboratory methods for use within the program is often tied directly to the types of shellfish species used during the original single lab validation studies. Prior to 2019, in order to expand the use of a method to a different type of shellfish, one had to do the same amount of validation work as if they were submitting a brand new method for approval.

Considering that, in these circumstances, the method has already been shown to work well with certain shellfish species, a proposal was introduced and adopted at the 2019 Biennial Meeting reducing the amount of work necessary to validate a method for use with a new shellfish matrix. Unfortunately, that proposal used the term “species” instead of “matrix” within the updated Constitution, Bylaws, and Procedures passage, which led to concerns that individuals are required to conduct matrix extension studies for each individual species of shellfish covered within the program, which was not the intent.

In order to address these concerns, the Laboratory Committee was charged with updating the matrix matrix extension guidelines to more clearly define the expectations and requirements.

Findings/Conclusions: This proposal seeks to modify the Constitution, Bylaws, and Procedures to replace the word “species” with “matrix” throughout the appropriate passage, and to point the user in the direction of guidance documents designed to help determine when a matrix extension is necessary. The proposal also seeks to update Chapter 2, .20 of the guidance documents, and to introduce a new guidance documents section, .21 – Laboratory Method Matrix Extensions. This new guidance document section includes a table grouping all shellfish species covered under the program into different matrix categories with intent of making it easier for users to determine which shellfish species are included in existing laboratory method approvals, and when a matrix extension might be necessary. This proposal was granted interim approval by the Executive Board in April 2022, and the proposal document, matrix category table, and an Excel file with some of the data used to determine the matrix groupings, are all appended to this report as Attachments 11, 12, and 13.

Recommendation: The Laboratory Committee recommends that Task Force 1 adopt this proposal as submitted.