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Standard Guide for Conducting Hazard Analysis-Critical Control Point (HACCP) Evaluations[1]

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1. Scope

1.1 This guide describes a stepwise procedure for using existing information, and if available, supporting field and laboratory data concerning a process, materials, or products potentially linked to adverse effects likely to occur in the environment as a result of an event associated with a process such as the dispersal of a potentially invasive species or the release of material (for example, a chemical) or its derivative products to the environment. Hazard Analysis-Critical Control Point (HACCP) evaluations were historically linked to food safety (Hulebak and Schlosser W. 2002 (**1**);[2] Mortimer and Wallace 2013 (**2**)), but the process has increasingly found application in planning processes such as those occurring in health sciences ; Quattrin et al. 2008 (**3**); Hjarno et al. 2007 (**4**); Griffith 2006 (**5**) or; Noordhuizen and Welpelo 1996 (**6**)), in natural resource management (US Forest Service 2014 a,b,c (**7, 8, 9**), (US EPA, 2006 (**10**); see also

http://www.fws.gov/ fisheries/ans/ANS-HACCP.html; http://www.haccp-nrm.org/; or http://www.waterboards.ca.gov/water_issues/programs/swamp/ais/prevention_planning.shtml (last accessed June 16, 2014)

or in supporting field operations wherein worker health and natural resource management issues intersect (see, for example,

http://www.haccp-nrm.org/plans/nm/negrito.pdf related to field operations occurring in areas associated with incidence of hantavirus; (last accessed June 15, 2014)

1.2 HACCP evaluation is a simple linear process or a network of linear processes that represents the structure of any event; the hazard analysis (HA) depends on the data quality and data quantity available for the evaluation process, especially as that relates to critical control points (CCPs) characterized in completing HACCP. Control measures target CCPs and serve as limiting factors or control steps in a process that reduce or eliminate the hazards that initiated the HACCP evaluation. The main reason for implementing HACCP is to prevent problems associated with a specific process, practice, material, or product.

1.3 This guide assumes that the reader is knowledgeable in specific resource management or engineering practices used as part of the HACCP process. A list of general references is provided for HACCP and implementation of HACCP and similar methods, as those apply to environmental hazard evaluation, natural resource management, and environmental engineering practices (**11-26**).

1.4 This guide does not describe or reference detailed procedures for specific applications of HACCP, but describes how existing information or other empirical data should be used when assessing the hazards and identifying CCPs potentially of use in minimizing or eliminating specific hazards. Specific applications of HACCP evaluation are included as annexes to this guide, which include implementation of HACCP in resource management practices related to control and mitigation of invasive species or disease agents primarily of concern for managing fish and wildlife.

1.5 HACCP evaluation has a well developed literature in, for example, food science and technology, and in engineering applications (see, for example, (**11, 12, 13, 15, 17**)). As a resource management tool, HACCP is relatively recent in application to the analysis of hazards to aquatic, wetland, and terrestrial habitats and the organisms occupying those habitats. (see, for example, US Forest Service 2014 a,b,c (**7, 8, 9**); see also http://www.haccp-nrm.org/ last accessed June 16, 2014). Most of the guidance provided herein is qualitative rather than quantitative, although quantitative methods should be applied to any hazard analysis when possible. Uncertainties associated with the analysis should also be characterized and incorporated into the HACCP evaluation when possible (see, for example, (**11, 27-38**)).

1.6 This standard provides guidance for assessing hazard within a generalized framework that may be extended to specific environmental settings, such as that detailed in E1023 for aquatic habitats (Guide for Assessing the Hazard of a Material to Aquatic Organisms and Their Uses). This standard

[1] This guide is under the jurisdiction of ASTM Committee E50 on Environmental Assessment, Risk Management and Corrective Action and is the direct responsibility of Subcommittee E50.47 on Biological Effects and Environmental Fate.

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[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

does not provide guidance on how to account for socio-economic or political considerations that influence the specification of the acceptability of risk associated with the hazard, particularly when HACCP is implemented and CCPs are considered within contemporary risk-based decision-making processes. Judgments concerning acceptability are outside the scope of this guide, but available guidance from ASTM is applicable to this process (see E2348 Standard Guide for Framework for a Consensus-based Environmental Decision-making Process).

1.7 This guide is arranged as follows:

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1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use and the implementation of HACCP. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E943 Terminology Relating to Biological Effects and Environmental Fate

E1023 Guide for Assessing the Hazard of a Material to Aquatic Organisms and Their Uses

E1391 Guide for Collection, Storage, Characterization, and Manipulation of Sediments for Toxicological Testing and for Selection of Samplers Used to Collect Benthic Invertebrates

E2348 Guide for Framework for a Consensus-based Environmental Decision-making Process

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *control, v*—to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

3.1.2 *control, n*—a state wherein correct procedures are being followed and criteria are being met.

3.1.3 *control measure*—any action and activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

3.1.4 *corrective action*—any action to be taken when the results of monitoring at the CCP indicate a loss of control.

3.1.5 *critical control point (CCP)*—a step at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level.

3.1.6 *critical limit*—a criterion which separates acceptability from unacceptability.

3.1.7 *deviation*—failure to meet a critical limit.

3.1.8 *flow diagram*—a systematic representation of the sequence of steps or operations of a system or process, including the production or manufacture of a materials or products.

3.1.9 *HACCP (Hazard Analysis-Critical Control Point)*—a system which identifies, evaluates, and controls hazards which are significant for a wide range of natural resource management and environmental engineering applications.

3.1.10 *HACCP plan*—a document prepared in accordance with the principles of HACCP to ensure control of hazards.

3.1.11 *hazard*—a biological, chemical or physical agent or condition with the intrinsic capacity to cause an unwanted or adverse effect in an exposed system.

3.1.12 *hazard analysis (HA)*—the process of collecting and evaluating data and information on hazards and conditions leading to their presence and necessary to include in a HACCP plan.

3.1.13 *monitor*—the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control.

3.1.14 *step*—a point, procedure, operation or stage in a process.

3.1.15 *validation*—obtaining evidence that the elements of the HACCP plan are effective.

3.1.16 *verification*—the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

3.2 For definitions of other terms used in this guide, refer to Terminology E943 and references cited herein.

4. Summary of Guide

4.1 Hazard Analysis-Critical Control Point (HACCP) evaluation has become increasingly applied to natural resource management and environmental engineering problems, particularly as hazards may be managed, for example, with respect to the safety of processes or release of materials or products to the environment. HACCP should be an integral part of management practices focused on engineering or resource management practices used to develop aquatic, wetland, and terrestrial habitats for human use (for example, agriculture or construction activities) or to enhance habitats for fish and wildlife. HACCP is a systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, rather than through end-product inspection and testing or retrospective engineering solutions necessitated because of previous undertakings. The HACCP system is intended for assessing and managing risks and safety concerns associated with a wide range of materials, products, and

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

management practices with an emphasis on a total systems approach to improve environmental quality. This standard could be used in conjunction with existing ASTM standards such as Guides E1023 and E2348. HACCP emphasizes control of a process as far upstream in the processing system as possible by utilizing operator control or continuous monitoring techniques, or a combination of both, at critical control points. The HACCP system uses the approach of controlling critical points in any process to reduce or eliminate risks and prevent safety problems from developing. The identification of specific hazards and measures for their control to ensure the safety of a process, material, or product through prevention and reduces the reliance on end-product inspection and testing (for example, for agrichemicals), remedial measures (for example, related to construction practices), or mitigation measures as part of a control program (for example, quarantine or disinfection for control of invasive species) are integral components of any HACCP system. Any HACCP system should be capable of accommodating change, such as advances in equipment design or developing alternative resource management practices, changes in processing procedures, or technological developments.

4.2 This guide describes an iterative procedure for assessing hazard and characterizing CCPs. Unavailable, yet necessary information concerning the hazard and the process generating that hazard should be identified and characterized through a stepwise evaluation that details the hazard and specifies critical points that may serve to control the process, and minimize or eliminate hazard. At the end of any iteration of the HACCP process, specific CCPs that reduce likelihood of hazard may be identified, or the available data related to the hazard and the process generating that hazard may be judged as being insufficient to adequately characterize hazard or CCPs. In the latter instance, additional data or information should be identified and obtained, so that HA and CCPs can be reassessed. The process is repeated until the hazard is adequately characterized and CCPs are characterized in order to reduce likelihood that hazard is realized.

4.3 Three annexes are also included with this standard guide.

4.3.1 Annex A1 focuses on implementation of HACCP within the context of natural resource management, principally that process developed for control of invasive species; principally, prevention of species invasions, but also mitigation, reduction, or eradication if such events have occurred. This annex summarizes extension of the general guidance contained within the standard guide to a specific application of the HACCP process that may serve as a "stand alone" document to support the development of species-specific or practice-specific HACCP plans linked to invasive species. The relationships between the generalized HACCP process summarized in the standard guide and its specific implementation in this annex should be considered in adapting HACCP plans to changing environmental conditions that might develop and alter hazards through time. Tasks outlined in the standard guide have been variously incorporated into the implementation-specific five-step HACCP process summarized in this annex. Additionally, in recognizing the dynamic process associated with species invasions, users of this stand-alone annex would benefit from consultation with online resources that directly complement this implementation of HACCP (http://www.haccp-nrm.org/ last accessed June 16, 2014).

4.3.2 Annex A2 continues implementation of HACCP linked to invasive-species management issues with a particular focus on decontamination procedures intended to mitigate or reduce hazards associated species transfers stemming from field operations. Given the increasing occurrence of dispersal and establishment of invasive species in previously unoccupied terrestrial or aquatic habitats, various organizations have developed procedures for managing unintended human-aided dispersal events. For aquatic invasive species (AIS) HACCP or principals characteristic of the HACCP process reflected in this annex guides the development of mitigation practices intended to prevent the spread of AIS with a primary focus on New Zealand mudsnail (*Potamopyrgus antipodarum*), quagga mussel (*Dreissena rostriformis bugensis*) or zebra mussel (*Dreissena polymorpha*). These invasive molluscs are not easily observed in field settings; hence, unintended transport to new locations on equipment or other materials used in the field serve as potential vectors mediating transfers from occupied habitats to previously unoccupied habitats when equipment or other materials are deployed in areas that are geographically separated, yet potentially linked through management actions mediated by their use. To prevent their unintended spread between field-work locations, procedures for decontaminating equipment and other materials are considered in this annex which serves to mitigate and reduce species transfers linked to use of this equipment or other materials in waterbodies at different locations. Procedures listed in this annex may be used to establish mitigation practices implemented through the decontamination process.

4.3.3 Annex A3 applied HACCP to natural resource management issues related to disease agents, particularly the transfer of pathogens between and among different locations within aquatic systems—lentic or lotic. A wide range of disease agents are capable of entering previously unoccupied habitats through actions of biological vectors or other transfer agents that assure their potential passage through numerous pathways. In the wild and in absence of human intervention, little direct control can be exerted over most of these pathways where waterfowl or shore birds, other migratory birds, foraging ungulates and other wildlife such as beavers may be critical components in completed pathways. In managed habitats or in managed field investigations, however, transfers of disease agents may be enabled when these disease-specific biological vectors or tools and other equipment serve as mediating agents; vectors for a wide array of pathogenic microorganisms are many, yet common attributes of biological or physical transfer agents benefit development of countermeasures that potentially mitigate transfers by interrupting pathways at CCPs in the chain-of-events required for successful species invasions or transfers of disease agents from one area to another, oftentimes previously unoccupied area. This annex focuses on a disease agent of amphibians—chytrid fungus, *Batrachochytrium dendrobatidis*—which calls for countermeasures that would

also mitigate disease agent transfers coincident with management of other aquatic biota.

5. Significance and Use

5.1 HACCP is a proactive management tool that serves to reduce hazards potentially expressed as adverse biological or environmental effects, for example, associated with chemical releases, changes in natural resource or engineering practices and their related impacts, and accidental or intentional releases of biological stressors such as invasive species.

5.2 Sequential implementation of HACCP and feedback in the iterative HACCP process allows for technically-based judgments concerning, for example, natural resources or the use of natural resources. Implementing the HACCP process serves to reduce adverse effects potentially associated with a particular material or process, and provides guidance for testing and evaluation of products or processes, through a pre-emptive procedure focused on information most pertinent to a system's characterization. For example, identification of CCPs assure that processes and practices can be managed to achieve hazard reduction. For different processes and situations, HA may be based on substantially different amounts and kinds of, for example, biological, chemical, physical, and toxicological data, but the identification of CCPs serving to reduce hazard is key to successful implementation of HACCP.

5.3 HACCP should never be considered complete for all time, and continuing reassessment is a characteristic of HACCP evaluations, especially if there should be changes in, for example, production volumes of a material, or its use or disposal increases, new uses are discovered, or new information on biological, chemical, physical, or toxicological properties becomes available. Similarly, HACCP should be considered an ongoing process serving as a key component in engineering practices, for example, related to construction activities and land-use changes, and natural resource management practices, for example, related to habitat use, enhancement, and species introductions such as fish-stocking programs. Periodic review of a system's performance will help assure that new circumstances and information receive prompt and appropriate attention.

5.4 In many cases, consideration of adverse effects should not end with completion of the HA and identification of CCPs key to the development of control measures. Additional steps may subsequently include risk assessment, and decisions concerning acceptability of identified hazards and risks, and mitigation actions potentially applicable to the process or practice that initially motivated HACCP.

6. Basic Concepts of Hazard Analysis-Critical Control Point (HACCP) Evaluation

6.1 *Overview of HACCP Evaluation*—The basic principle of HACCP relies on system characterization and a repetitive or iterative evaluation of that system and its attendant outcomes. When available data to characterize a system are inadequate and CCPs can not be adequately characterized, data needs are identified and HACCP reiterated. The process is repeated until HA is adequate and CCPs are clearly identified. The HACCP system systematically identifies hazards and measures for their control to ensure the safety of any process, but especially those involving engineering or management practices that manipulate materials, products, or systems potentially associated with adverse effects directly or indirectly associated with those manipulations. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing and inspection. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments. This section reviews the 12 tasks in the application of HACCP, including the seven HACCP principles. It emphasizes the importance of standards and guidelines as a basis for developing the HACCP plan.

6.2 *Principles of the HACCP System*—The HACCP system consists of seven principles that guide any evaluation.

6.2.1 Conduct a hazard analysis. Identify the potential hazard(s) associated with at all stages or steps within a system or process of concern within a system. Assess the likelihood of occurrence of the hazard(s) and identify the measures for their control.

6.2.2 Determine the Critical Control Points (CCPs). Determine the points, procedures or operational steps that can be controlled to eliminate the hazard(s) or minimize its (their) likelihood of occurrence. A "step" means any stage in the system, including materials or processes that are part of the system or contribute to the systems form or function, for example, exogenous inputs should have specifications that can be incorporated into HACCP.

6.2.3 Establish critical limit(s). Critical limit(s), also referred to as control limit(s), must be established to ensure the CCP is under control.

6.2.4 Establish a system to monitor control of the CCP. Establish a system to monitor control of the CCP by scheduled testing or observations.

6.2.5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

6.2.6 Establish procedures for verification to confirm that the HACCP system is working effectively.

6.2.7 Establish documentation concerning all procedures and records appropriate to these principles and their application.

6.3 *Implementation of the HACCP System*—Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to existing technical practices, the role of processes to control hazards, likely end-use of the product (for example, if hazards are associated with manufacturing process), categories of users of concern, and data suggestive of a system being out of control (for example, observation of system failure). The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found. In complex systems, HACCP should be applied to each specific operation separately. CCPs identified in any given specific implementation might not be the only ones identified for a specific application or might be of a different nature; hence, HACCP

will vary as a function of the system. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying HACCP to be flexible where appropriate, given the context of the application, taking into account the nature and the size of the operation.

6.3.1 *Application of HACCP Principles*—Implementation of HACCP principles is captured in the Logic Sequence for Application of HACCP (Fig. 1).

6.3.1.1 Assemble HACCP team. Appropriate process-specific or material-specific knowledge and expertise must be available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multi-disciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified, including the general classes of hazards to be addressed (for example does it cover all classes of hazards or only selected classes).

6.3.1.2 Describe product or process. A full description of the product or process of concern should be developed.

6.3.1.3 Identify intended use. The intended use should be based on the expected uses of the product or services that will result from completion of an engineering project that may variously affect end users or consumers. In specific cases, vulnerable groups should be considered.

6.3.1.4 Construct flow diagram. The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation, for example, associated with a product, material, or engineering activity. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

6.3.1.5 On-site verification of flow diagram. The HACCP team should confirm the processing operation against the flow diagram during all stages of operation and amend the flow diagram where appropriate.

6.3.1.6 List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards as supported by Principle 1. The HACCP team should list all hazards that may be expected to occur at each step of the process, for example, from primary production, processing, manufacture, and distribution until the point of use. The HACCP team should next conduct a hazard analysis to identify and describe for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of product or to the engineering process. In conducting the hazard analysis, the following should be included whenever possible: the likely occurrence of hazards and severity of their adverse effects; the qualitative or quantitative evaluation, or both, of the presence of hazards; and conditions leading to the above. The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

6.3.1.7 Determine Critical Control Points (CCP). There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree which indicates a logic reasoning approach, as illustrated in Annex A1. Application of a decision tree should be flexible,

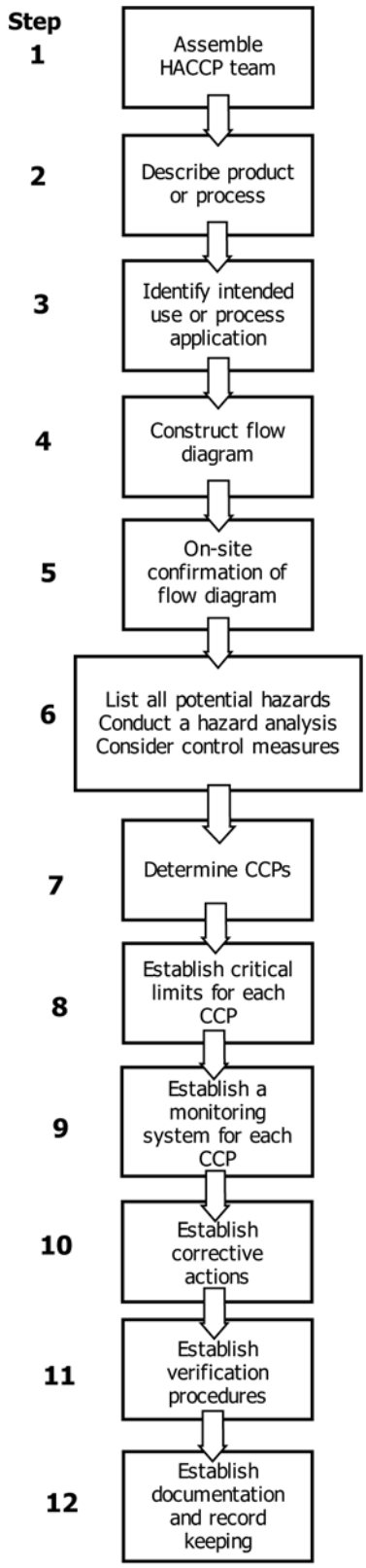

FIG. 1 Overview of HACCP Process

given whether the operation production or outcomes of the process being evaluated. The decision tree could be used for guidance when determining CCPs, although a decision tree may not be applicable to all situations. Other approaches may be used, and training in the application of the decision tree is recommended, if that approach to HACCP is pursued. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

6.3.1.8 Establish critical limits for each CCP. Limits must be specified and validated if possible for each CCP. In some cases more than one critical limit will be elaborated at a particular step. Criteria may capture upper and/or lower bounds of acceptable performance, and may be specified by indicators benchmarked on past performance.

6.3.1.9 Establish a monitoring system for each CCP. Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide data in real-time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP d in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes or real-time activities that may not allow for lengthy analytical testing. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s).

6.3.1.10 Establish corrective actions. Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control, including actions that must be taken for proper disposition of the affected product, for example, in the food industry. Deviation and product disposition procedures must be documented in the HACCP record keeping similar in practice to establishing risk management practices wherein acceptable risk is characterized.

6.3.1.11 Establish verification procedures. Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include: review of the HACCP system and its records; review of deviations and product dispositions; confirmation that CCPs are kept under control. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

6.3.1.12 Establish documentation and record keeping. Efficient and accurate record keeping is essential to the application of an HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation. Documentation examples are hazard analysis; CCP determination; Critical limit determination. Record examples are: CCP monitoring activities; Deviations and associated corrective actions; Modifications to the HACCP system.

6.4 *Expanded Characterization of HACCP Process*—The first task in the application of HACCP is to assemble a team having the knowledge and expertise to develop an HACCP plan. The team should be multidisciplinary and should represent a blend of expertise and experience. The assembled team will collect, collate and evaluate technical data and identify hazards and critical control points. One person may fulfill several roles or even constitute the whole team, in which case the use of external consultants or advice may be necessary. The team should include personnel who are directly involved in daily activities related to the hazards of concern, since these individuals will be more familiar with the specific variability and limitations of the operation or materials in question. The HACCP team may require independent outside experts to advise on identified issues or problem areas; however, complete reliance on outside sources is not recommended in developing the HACCP plan. Ideally the team should not be larger than six, although for some implementations of HACCP, it may be necessary to develop larger teams.

6.4.1 *Team Composition*—When selecting the team, the coordinator should focus on those who will be involved in hazard identification, those who will be involved in determination of critical control points, those who will monitor critical control points, those who will verify operations at critical control points, those who will examine samples and perform verification procedures.

6.4.2 *Knowledge Required*—In addition to knowledge of HACCP principles and techniques, personnel participating as part of the HACCP team should have a basic understanding of technology and procedures characteristic of the process or material that initiated the HACCP evaluation, as well as a basic understanding of the particular hazard(s) that the plan will address.

6.4.3 *Scope*—One of the first tasks of the HACCP team should be to identify the scope of the HACCP plan. The team should limit the study to a specific material and process, define the type(s) of hazards to be included (for example biological, chemical, physical), define the system or part of the system to be studied.

6.4.4 *Coordinator*—The team must include a coordinator (chairperson) whose role is to ensure that the composition of the team meets the needs of the study, suggest changes to the team if necessary, coordinate the team's work, ensure that the agreed established plan is followed, share the work and responsibilities, ensure that a systematic approach is used, ensure that the scope of the study is met, chair meetings so that team members can freely express their ideas, represent the team before management, provide management with an estimate of the time, money and labor required for the study.

6.4.5 *Develop a Flow Diagram*—It is easier to identify hazards and CCPs to suggest methods of control and to discuss these among the HACCP team if there is a flow diagram of the system linked to the hazard of interest. The review of the flow of materials or the process in the system from the beginning to end is the feature that makes HACCP a specific and important tool for the identification and control of potential hazards. A process flow diagram should be constructed following interviews, observation of operations and other sources of information, for example, such as engineering design or field operations manuals. The process flow diagram will identify the important process steps used in the production of the specific material or specific operation being assessed. There should be enough detail to be useful in hazard identification, but not so much as to overburden the plan with less important points.

6.4.6 *Hazard Analysis*—Hazard analysis is the first HACCP principle, and is one of the most important tasks of HACCP. An inaccurate hazard analysis would inevitably lead to the development of an inadequate HACCP plan. Hazard analysis requires technical expertise and scientific background in various domains for proper identification of all potential hazards.

6.4.7 *Critical Control Points and Critical Limits*—At each CCP critical limits are established and specified. Critical limits are defined as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether a process is producing materials or conducting specific operations in a safe manner. Critical limits may be set for factors, for example, such as temperature, time (minimum time exposure), physical dimensions, as these attributes affect system performance. These parameters, if maintained within boundaries, will confirm the safety of the system of interest.

6.4.8 *Monitoring*—Monitoring is the process that users rely upon to show that the HACCP plan is being followed. It provides the user with accurate records that demonstrate that the conditions of system are in compliance with the HACCP plan. Ideally, monitoring should provide information in time to allow any adjustments to the process, thus preventing loss of control of the process and critical limits being exceeded. In practice, operating limits are often used to provide a safety margin which allows extra time to adjust the process before the critical limit is exceeded. There are many ways to monitor the critical limits of a CCP. Monitoring can be done on a continuous (100 percent) or batch basis. When feasible, continuous monitoring is preferred, since it is more reliable. Continuous monitoring is designed to detect shifts around target levels, thus allowing correction of these shifts and preventing deviation beyond the critical limits. When monitoring is not continuous, the amount and frequency of monitoring should be sufficient to provide an acceptable level of assurance that the CCP is under control. The higher the frequency of monitoring (that is, the less time between each instance of monitoring), the less system performance will be affected when there is a loss of control at the CCP. A further consideration when establishing a monitoring system is the time taken to achieve a result from the monitoring procedure. Most monitoring procedures will need to be rapid, since time for lengthy analytical testing may not be practical. For this reason physical and chemical measurements or visual observations, which may be done rapidly, are often preferred as monitoring tools. If analytical instrumentation is used in a monitoring program, it is essential that all monitoring equipment be properly calibrated for accuracy. Monitoring procedures performed during the operation should result in written documentation which will serve as an accurate record of the operating conditions. Monitoring records provide information on conditions during the operation and allow for action to be taken in the event of a loss of control or for a process adjustment to be made if there is a trend towards a loss of control. Accurate monitoring procedures and associated records provide information to the operator and allow for decisions to be made on the acceptability of the lot at a particular stage in the process. To complete the monitoring process, data derived from monitoring should be reviewed and evaluated by a designated person or persons with knowledge and authority to carry out corrective actions when indicated. The worst scenario is that in which monitoring procedures indicate that any one of the critical limits is exceeded, which indicates loss of control of a CCP. This lack of control is considered to be a deviation resulting in the production of a hazardous or unsafe product. The situation requires immediate identification and control of the affected product and corrective action. Responsibility for monitoring should be clearly defined, and individuals must be adequately trained in the monitoring procedures for the CCP for which they are responsible. They must also fully understand the purpose and importance of monitoring. The individual should have ready access to the monitoring activity, must be unbiased in monitoring and must accurately report the monitoring activity.

6.4.9 *Design of a Monitoring System and Establishing Corrective Actions*—Loss of control is considered as a deviation from a critical limit for a CCP. Deviation procedures are a predetermined and documented set of actions to be implemented when a deviation occurs. All deviations must be controlled by taking action(s) to control the non-compliant product or process and to correct the cause of non-compliance. Product or process control includes proper identification, control and disposition of the variance. The control and disposition of the variance and the corrective action(s) taken must be recorded and filed. The diversity of possible deviations at each CCP means that more than one corrective action may be necessary at each CCP. When a deviation occurs, it will most likely be noticed during the routine monitoring of the CCP. Deviation and corrective action procedures are prescribed so that employees responsible for CCP monitoring understand and are able to perform the appropriate corrective action(s) in the event of a deviation. Process adjustments should also be made when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process within the operating limits before a deviation occurs. The deviation procedures at each CCP should be recorded.

6.4.10 *Deviation and Corrective Action Procedures*—Since the main reason for implementing HACCP is to prevent problems from occurring, corrective action should be taken to prevent deviation at a CCP. Corrective action should be taken following any deviation to ensure the safety of the product or

process, and to prevent recurrence of the deviation. Corrective action procedures are necessary to determine the cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure that the action taken is effective. If the corrective action does not address the root cause of the deviation, the deviation could recur. Reassessment of the hazard analysis or modification of the HACCP plan may be necessary to eliminate further occurrence.

6.4.11 *Deviation and Corrective Action Records*—Records should be available to demonstrate the control of products affected by the deviation and the corrective action taken. Adequate records permit verification that the producer has deviations under control and has taken effective corrective action.

6.4.12 *Deviation Procedures and Verification*—Verification is embodied in HACCP principles, and serve to determine compliance with the HACCP plan by using methods, procedures, tests and other evaluations as needed, in addition to monitoring. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. Careful preparation of the HACCP plan with clear definition of all the necessary items does not guarantee the plan's effectiveness. Verification procedures are necessary to assess the effectiveness of the plan and to confirm that the HACCP system adheres to the plan. Verification allows the producer to challenge the control measures and to ensure that there, is sufficient control for all possibilities; for example, verification may ensure that adequate contingency procedure plans are in place when critical limits are exceeded at a CCP. Verification should be undertaken by an appropriately qualified individual or individuals who are capable of detecting deficiencies in the plan or its implementation. Verification should be undertaken at the completion of the HACCP study; whenever there is a change in product, ingredients, process, etc.; when a deviation occurs; in the event of newly identified hazards; and at regular predetermined intervals. Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities.

6.4.13 *Description of Verification Activities*—Each HACCP plan should include verification procedures for individual CCPs and for the overall plan. HACCP plans are expected to evolve and to improve with experience and new information. Periodic verification helps improve the plan by exposing and strengthening weaknesses in the system and eliminating unnecessary or ineffective control measures. Verification activities include HACCP plan validation, HACCP system audits, equipment calibration, targeted sample collection and testing.

6.4.14 *HACCP Plan Validation*—Validation is the act of assessing whether the HACCP plan for the particular product and process adequately identifies and controls all significant hazards or reduces them to an acceptable level. HACCP plan validation should include review of the hazard analysis, CCP determination, justification for critical limits, based for example on current good science and regulatory requirements, determination of whether monitoring activities, corrective actions, record keeping procedures and verification activities are appropriate and adequate, validation involves ensuring that the HACCP plan is based on methods and information sufficient to identify hazards and identify CCPs, and is appropriate for the system of interest. A technical review should be performed to ensure that there is a scientific and technical basis for decisions regarding which hazards are being controlled, which hazards are not being controlled and how identified hazards are being controlled. This review could incorporate the use of information and data gathered for the purpose of the verification, and should be periodically updated. The process of validating an existing HACCP plan should also include review of HACCP audit reports, review of changes to the HACCP plan and the reasons for those changes, review of past validation reports, review of deviation reports, assessment of corrective action effectiveness, review of information on consumer complaints, review of linkages between the HACCP plan and good management practice (GMP) programs. HACCP plan validation is an ongoing, periodic procedure. Validations may be scheduled at a pre-set frequency. However, other factors may trigger a review of the plan to determine if changes are necessary. These factors could include changes to the raw materials, product or process; adverse audit findings; recurring deviations; new scientific information about potential hazards or control measures; and user complaints and/or failures or under performance of the system.

6.4.15 *HACCP System Audits*—As part of verification, audits are performed to compare the actual practices and procedures of the HACCP system with those written in the HACCP plan. Audits are systematic and independent examinations involving on-site observations, interviews and review of records to determine whether the procedures and activities stated in the HACCP plan are implemented in the HACCP system. These examinations are usually performed by one or more independent persons who are not involved in implementation of the HACCP system. Audits may be performed for individual CCPs and/or for the overall plan. On-site observation may include, for example, visual inspection to ensure that system description and flow chart are accurate, monitoring required by the HACCP plan at the CCPs is performed, processes are operating within established critical limits, records are filled out accurately and at the time observations are made. Records to be reviewed during auditing of the HACCP plan include, for example, those demonstrating that monitoring activities have been performed at the locations specified in the HACCP plan, monitoring activities have been performed at the frequencies specified in the HACCP plan, affected systems have been controlled and corrective actions have been taken whenever monitoring has indicated the occurrence of a deviation from critical limits, equipment has been calibrated at the frequencies specified in the HACCP plan. Audits should occur frequently enough to ensure that the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and materials.

6.4.16 *Calibration*—Calibration involves checking instruments or equipment against a standard to ensure accuracy. Calibration should be documented and the records should be available for review during verification. Calibration of appropriate equipment and instruments used in the development and, implementation of the HACCP plan should be carried out,

during monitoring or verification, or both, at a frequency sufficient to assure continuous accuracy, according to procedures established in the HACCP plan (which can be based on instrument or equipment manufacturer specifications), by checking accuracy against a recognized standard, under conditions similar or identical to those under which the instrument or equipment will be used. Calibration of CCP monitoring equipment is important; if the equipment is out of calibration, then monitoring results will not be accurate and may be completely unreliable. When the equipment monitoring a CCP is out of calibration, the CCP is considered to have been out of control since the last documented calibration.

6.4.17 *Targeted Sample Collection and Testing*—Verification may also include targeted sampling and testing and other periodic activities. Targeted sampling and testing involves taking samples of materials or products periodically and testing them to ensure that critical limits are appropriate for product safety. Targeted sampling may be carried out to check vendor compliance when receipt of material is a CCP and purchase specifications are relied on as critical limits. When critical limits are set for equipment operation, materials or products may be sampled to ensure that the equipment settings are appropriate. When sampling and testing is used as a verification tool, the usefulness of the test often depends on how the material is sampled. The risk and level of confidence needed will determine the sample size and the method of sample collection.

6.4.18 *Verification Frequency*—Verification activities should be performed according to a pre-established schedule described in the HACCP plan or whenever there are indications that the system status may have changed. These indications may include observations that CCPs may not be operating within critical limits, record reviews indicating inconsistent monitoring, record reviews indicating that CCPs are repetitively operated outside critical limits, user complaints, or acquisition of data previously unavailable for the evaluation. Verification procedures should be scheduled at a frequency that ensures that the HACCP plan is being followed continuously and that measurements remain accurate within established limits. Thus, the length of time between scheduled verification activities should match the level of confidence in the continuous and accurate performance of the HACCP plan. The frequency of verification activities may change over time. A history of verification activities indicating that the process is consistently in control may support safe reduction of the frequency of verification activities.

6.4.19 *Records of Verification*—Verification activities should be documented in the HACCP plan. Records should be made of the results of all verification activities. Records of verification should include methods, date, individuals and/or organizations responsible, results or findings and action(s) taken. Verification procedures for the overall HACCP plan should be documented in a file for the HACCP plan.

6.4.20 *Regulatory Verification*—Verification should be a routine part of regularly scheduled government inspections, if those activities are included in the HACCP plan. Regulatory verification should also involve review and/or audit of the adherence to the HACCP system to its HACCP plan. Compliance actions should be taken when regulatory verifications indicate deficiencies in the HACCP plan or implemented HACCP system.

6.4.21 *Documentation and Record Keeping*—Records are essential for reviewing the adequacy of the HACCP plan and the adherence of the HACCP system to the HACCP plan. A record shows the process history, the monitoring, the deviations and the corrective actions that occurred at the identified CCP. It may be in any form, for example processing chart, written record, computerized record. The importance of records to the HACCP system cannot be overemphasized. It is imperative that the producer maintain complete, current, properly filed and accurate records. Four types of records should be kept as part of the HACCP program: support documentation for developing the HACCP plan, records generated by the HACCP system, documentation of methods and procedures used, records of employee training programs.

6.4.21.1 *Support Documents*—HACCP plan support documents include information and support data used to establish the HACCP plan such as the hazard analysis and records documenting the scientific basis for establishing the CCPs and critical limits. Examples include data used to establish the control measures and data used to establish the adequacy of critical limits. Support documents should also include a list of the HACCP team members and their responsibilities, as well as all the forms produced during the preparation of the HACCP plan. Including description of materials, process, or system of concern, flow diagram, hazard analysis, identification of CCPs, identification of the critical limits for each CCP (including data from experimental studies or information collected to support the critical limits), documented deviation and corrective action plans, planned verification activities and procedures, and identification of the preventive measures for each hazard. Support documents may also include correspondence with consultants, as well as documents detailing how the HACCP plan was developed.

6.4.21.2 *Records Generated by the HACCP System*—HACCP system records are kept to demonstrate adherence of the HACCP system with the HACCP plan. These records are used to demonstrate control at CCPs. By tracking records generated by the HACCP system, a system user can become aware that a process is approaching its critical limit. Review of records can be instrumental in identifying trends and in making operational adjustments. Timely corrective action can be taken if a critical limit is violated. The required HACCP records to be kept at each CCP should be written, for example, on standard forms. Failure to document the control of a CCP would be a critical departure from the HACCP plan. The records generated by the HACCP system include all activities and documentation required by the plan, as follows:

(1) Monitoring Records for All CCPs—All HACCP monitoring records should be kept on forms that contain the following information: form title, time and date, process or material identification, critical limits, monitoring observation or measurement, operator's signature or initials, corrective action taken, where applicable, and reviewer's signature or initials with date of review.

(2) Deviation and Corrective Action Records—These records should document variance from acceptable limits with identification of the deviation, nature and extent of deviation, information on the disposition of outcomes occurring during deviation, and description of the corrective action with documentation of return to acceptable performance.

(3) Verification/Validation Records—Verification and validation may be documented through in-house on-site inspections, equipment testing and evaluation, accuracy and calibration of monitoring equipment, and results of verification activities (including methods, date, individuals and/or organizations responsible, results or findings and action taken).

ANNEXES

(Mandatory Information)

A1. HACCP APPLIED TO PREVENTION AND CONTROL OF INVASIVE SPECIES

A1.1 Background

A1.1.1 Implementation of the HACCP process has been incorporated into natural resource management practices focused on various aspects of invasive species, ranging from prevention programs to control and mitigation. Annex A1 summarizes HACCP and its application to the prevention and control of invasive species. This annex extends the general guidance contained within this standard to a specific application of the HACCP process. The annex may serve as a "stand alone" document to support the development of species-specific or practice-specific HACCP plans developed in response to natural resource management needs linked to invasive species. The relationships between the generalized HACCP process summarized in the standard and its specific implementation in this annex, however, should be considered in adapting HACCP plans to, for example, changing environmental conditions that might develop and alter hazards through time. Tasks outlined in the standard guide have been variously incorporated into the implementation-specific five-step HACCP process which was framed within the context of the guiding principles of HACCP specified in this standard. Additionally, in recognizing the dynamic process associated with species invasions, users of this stand-alone annex would benefit from consultation with online resources that directly complement this implementation of HACCP (http://www.haccp-nrm.org/ last accessed June 16, 2014).

A1.1.2 *Managing Natural Resource Pathways*—In natural resource work, equipment and organisms are often moved from one location to another. The specific equipment or organism being moved is called the target. Targets could include animals for relocation or stocking for recreation, equipment such as a bulldozers and backhoes, sampling gear such as nets or traps, and even people. Transporting targets provides a potential vector for the spread of non-target species that could potentially invade new habitat. Non-target species are the plants, animals, diseases, pathogens and parasites that are not intended to be moved. Natural resource managers participate in the first-line of defense to remove these hazards from pathways. Resource management work often creates open pathways that could spread invasive species to unique and critical habitats for already endangered species. Next to habitat loss, invasive species are resource management's biggest challenge. Executive Order 13112[4] (1999) directs agencies to prevent the spread of invasive species in their work but few management tools exist to implement this Directive. HACCP planning has been modified from systems engineering and food industry applications for natural resource work. Around the world industry uses the HACCP planning tool to remove product contamination. In natural resource pathways, hitchhiking species are considered contaminants. HACCP's comprehensive planning identifies these species and the risk of contamination while documenting the best management practices used to prevent and remove hitchhikers.

A1.1.3 HACCP planning focuses attention on critical control points where non-target species can be removed. Documenting risks and methods used to remove non target species gives managers a strategic method to make consistent decisions based on identified risks. Planning builds a logical framework of information to weigh risks for species spread against management benefits.

A1.2 Introduction

A1.2.1 Natural resource management (NRM) agencies work with species and supporting habitats collecting data and defining species health. This field work may also provide pathways to unintentionally spread species. Hitchhiking "non-target" species moved to new locations could become invasive species management issues in the future. Pillsbury's HACCP (Hazard Analysis and Critical Control Point) planning has been modified as a pathway management tool to prevent spreading non-target species. HACCP's strategic planning process removes hazards (contaminants) at critical control points. In natural resource work, non-target, hitchhiking species of plants, animals, diseases, pathogens and parasites are pathway concerns. Some examples include collecting and moving plants or animals (targets) for preservation, relocation, restoration or for recreation. Similarly, equipment used in field activities such as pickups, bulldozers, backhoes, and sampling gear such as nets or traps, and clothing serve as pathways to spread species. HACCP Plans document: who, what, why, where, when, and how.

[4] Office of the President, 1999, Executive Order 13112, February 3, 1999 established Invasive Species Council and specified its duties.

A1.2.2 As a framework for strategic thinking, HACCP focuses planning attention on critical control points (CCPs) where non-target species can be prevented and removed. Documented risks and methods used to remove hitchhiking species give managers reliable information to make consistent decisions based on identified risks. Implementation of well designed and implemented plans allows decision makers to weigh risks for species spread against management benefits. For some pathways, identified risks may outweigh benefits until better removal procedures are identified. This is a condensed version of the training manual on-line at the HACCP support website www.HACCP-NRM.org (last accessed July 6, 2009). Forms, guides, training announcements, links, a searchable database of plans and a downloadable planning wizard are available at the support site, including points of contact to support work with HACCP Planning Wizard Version 2.04 (http:/www.haccp-nrm.org/Wizard/default.asp last accessed September 2, 2014.)

A1.3 HACCP Planning

A1.3.1 A team approach to HACCP planning helps make sure important steps were not overlooked. As indicated in general guidance included in this standard, the seven principles of HACCP may be considered through various implementations. For this implementation of HACCP focused on prevention and control invasive species, a five-step process was developed as indicated below:

Step 1—Describe the activity.
Step 2—Identify potential hazards.
Step 3—Diagram the sequential actions in step 1.
Step 4—Analyze the hazards identified in step 2.
Step 5—Complete the HACCP plan.

A1.3.2 *Describe the Activity*—HACCP team describes the activity, the method of accomplishing the activity, and the intended purpose and need for the activity. The activity should describe a discrete work action and not try to cover all station operations and objectives. HACCP planning will only work for specific actions, for example, raising and stocking fish or conducting habitat surveys (aquatic and terrestrial).

A1.3.3 *Identifying Hazards*—Hazards or non-target species that may contaminate pathways and hitchhike to new habitats could include vertebrates, invertebrates, plants, or other biologics (for example, diseases, pathogens, and parasites). Identify the potential hazards into four classes: vertebrates, invertebrates, plants, and others. Biologists, agencies, organizations and states may disagree on what significant hazards must be removed from specific pathways. Discussions here focus on planning objectives which will establish the foundation for each HACCP plan. The Step 4, Hazard Analysis Worksheet, will further sharpen the focus on non-target species that need to be removed from the pathway being reviewed.

A1.3.4 *Diagram the Sequential Actions in Step 1*—A flow diagram shows in block form the sequential tasks required to accomplish the activity. Simple, straightforward descriptions copied from the Activity Description, Step 1, work best. It is important to include all the tasks within the activity. The flow diagram should convey sufficient detail to characterize the activity or process to reviewers of the completed HACCP plan.

A1.3.5 *Hazard Analysis Worksheet*—The Hazard Analysis Worksheet organizes and documents considerations the team identified as hazards. Each task listed in the flow diagram (Step 3) is copied forward to column 1 in this form. Potential hazards identified in Step 2 are copied forward to column 2. Risk assessment results are recorded in column 3, with the justification for accepting or rejecting each potential hazard stated in column 4. Control measures are listed in column 5. Column 6 answers whether this task is a critical control point.

A1.3.5.1 *Analyzing Hazards*—Control measures need to be defined for significant hazards identified in this step. Each potential hazard should be assessed by considering risk (probability of occurrence) and severity. Base the estimate of risk on a combination of experience and of the pathway. Severity is the seriousness of a hazard. A good way to approach hazard analysis is to divide it into two activities: brainstorming and risk assessment. Brainstorming lists the hazards possible at each operational step. The Team uses their list of hitchhikers, or non-targets, to evaluate the risks and severity of each of the hazards if unintentionally moved to a new habitat. Planners then decide which hazards are significant and must be addressed by the HACCP plan. Planning focuses on significant hazards reasonably likely to occur unless specific control measures are in place. Control measures are actions that can be used to prevent or eliminate a hazard or reduce it to an acceptable level. A hazard must be controlled if *(1)* it is reasonably likely to occur, and *(2)* if not properly controlled, it is likely to result in an unacceptable risk of spreading non-target species to new habitats.

A1.3.5.2 *Identifying Critical Control Points*—For every significant hazard identified during the hazard analysis, there must be one or more critical control points (CCPs) where the hazard is best managed, for example, controlled or reduced through engineering practices. CCPs are points in the activity, or the pathway, where specified HACCP control actions are used to control significant hazards. Many points in the flow diagram not identified as CCPs are valuable control points where routine prevention measures help to achieve overall unnecessarily identified as CCPs. Only points identified as key to control significant hazards are considered CCPs. Differentiating between CCPs and control points varies from activity to activity and depends on the operation. When designating CCPs, any applicable state statutes that may dictate the identification of a CCP must be identified, for example, in some states it is illegal to transport certain non-targets overland. It may not be possible to fully eliminate or prevent a hazard. In some cases and with some hazards, minimization may be the only reasonable goal of the HACCP plan. Although hazard minimization is acceptable in some instances, it is important that all hazards be addressed. Any limitations of the HACCP plan to control those hazards should also be understood by resource management agencies and their partners. When HACCP plans cannot satisfactorily control hazards, other approaches to prevent the spread are required. Often, the best place to control a hazard is at the point of entry. But this is not always true. The CCP can be several steps away from the point at which the significant hazard is introduced. The CCP decision tree uses a series of four questions to help identify

CCPs. The decision tree can be found in the Pathway Management manual on the support website (see www.HACCP-NRM.org last accessed July 1, 2014). The planning wizard associated with this web site may help distinguish between CCPs from control points.

A1.3.5.3 *Establishing Controls*—One or more controls must be established for each CCP identified in the hazard analysis. Control boundaries or limits are defined to ensure non-targets are removed or prevented from entering the pathway. If the process deviates from the limits established for the control, corrective actions must be taken to make sure that non-targets do not slip past a critical control point. Testing combined with scientific information is used to establish critical limits. This reference material should become part of the HACCP Plan support documentation.

A1.3.5.4 *Setting Critical Limits*—The Team usually recommends controls which can be quantified and measured in concentrations, units of time or amounts of something for control effectiveness. Variations from these specifications would mean that contaminating species, hitchhikers, could slip through established controls. Limits need to be researched and clearly documented during planning so those implementing the HACCP plan generated in step 5 can effectively monitor efforts to avoid costly errors.

A1.3.6 *HACCP Plan Form*—From the Hazard Analysis Worksheet (Step 4) CCPs noted in column 6 are copied forward to the HACCP Plan Form. If no CCPs were noted then the planning is finished. Completing the HACCP Plan will describe techniques, methods, and treatments which will control the hazards identified in column 2. Monitoring specified critical limits can prevent corrective action by changing treatments before a critical limit is exceeded. Accurate records provide verification that HACCP procedures are effectively controlling hazards.

A1.3.6.1 *Corrective Actions*—Corrective Actions are usually written in an "if/then" format and should be implemented to re-established control as soon as a monitoring problem is noted. Corrective action should take care of immediate problems as well as provide long-term solutions. Routine critical limit failure means the HACCP plan needs to be updated.

A1.3.6.2 *Supporting Documentation*—The HACCP Plan Form has a column to note where supporting documentation regarding verification and records can be found.

A1.3.6.3 *Verification and Validation*—Verification is important in HACCP planning and execution. HACCP has spawned a new adage—"trust what you can verify". Verification ensures that procedures at CCP's are functioning. Regular review of calibrations, monitoring, and corrective action records let managers know if operating limits are removing non-target species. Verification should include tests to check that HACCP plans are working and being followed. In addition to verifying CCPs, HACCP planners should identify scheduled verification of the complete HACCP system. Validation, a component of verification, provides objective evidence that the plan is based on scientific information representing a valid approach to control spread of non-target species through resource management pathways. The HACCP team or outside reviewers should validate plan components before relying on the HACCP plan to control hazards. Planning strategies should be regularly reviewed and updated to incorporate new techniques.

A1.3.6.4 *Building a National Database of HACCP Plans*—HACCP planners have an opportunity to contribute to the science of natural resource work. Comprehensive HACCP plans document best management practices which describe methods and procedures used to prevent and remove non-target species. Sharing BMP's will help others doing similar work. A web-based reference library has been established so that shared plans can be easily searched for methods and procedures. BMPs should be compiled in a database available to other resource managers who may be addressing similar problems.

TABLE A1.1 HACCP Step 1—Activity

Activity Description	
Facility:	Site:
Project Coordinator:	Activity:
Site Manager:	
Address:	
Phone:	
Project Description	

TABLE A1.2 HACCP Step 2—Identify Potential Hazards

Hazards: Species Which May Potentially Be Moved/Introduced
Vertebrates:
Invertebrates:
Plants:
Other Biological agents (that is disease, pathogen, parasite):
Others (that is construction materials):

TABLE A1.3 HACCP Step 3

Flow Diagram Outlining Sequential Tasks to complete Activity/Project
Described in HACCP Step 1–Activity Description
to be transferred to column 1 of the HACCP Step 4–Hazard Analysis Worksheet

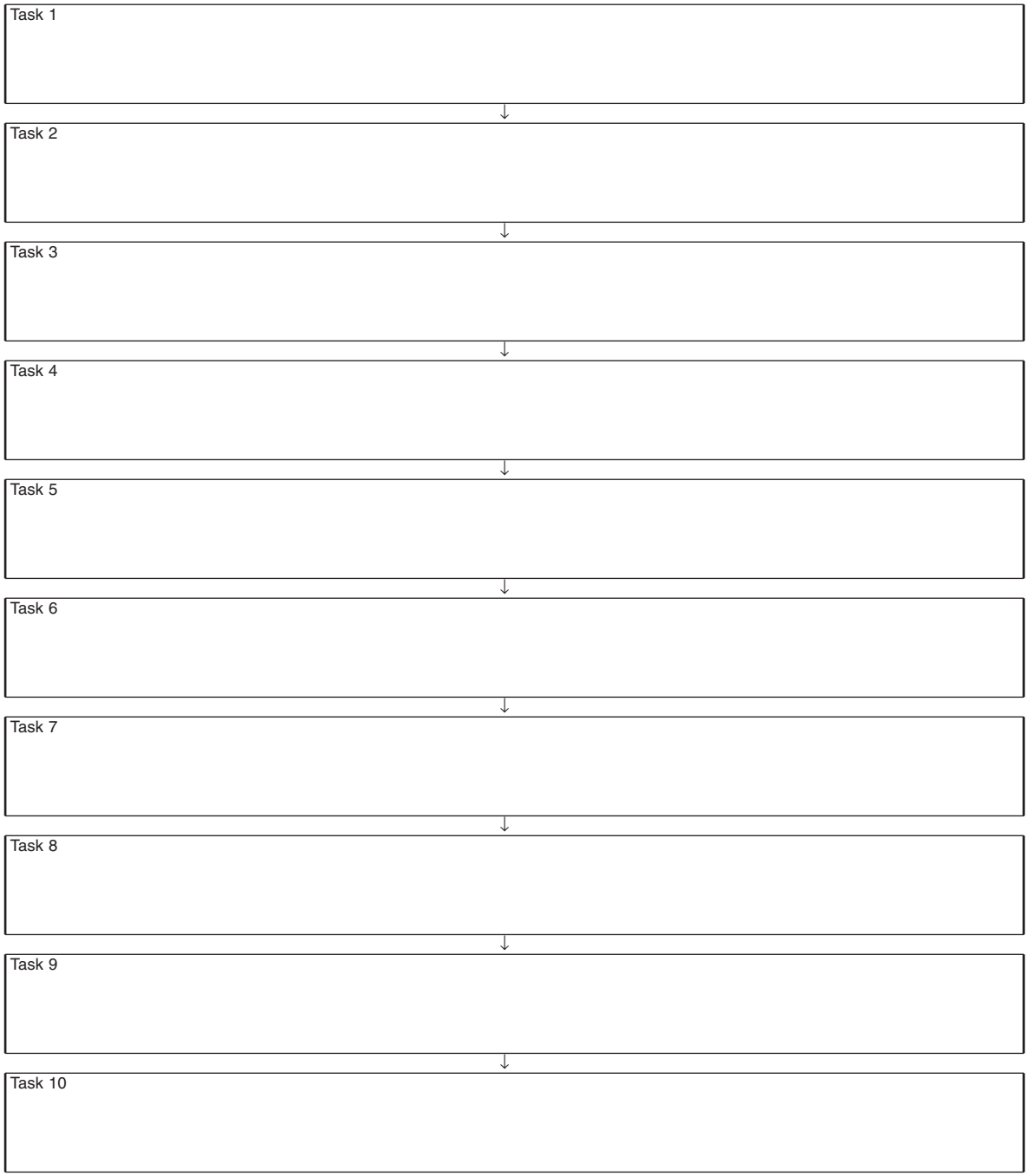

TABLE A1.4 HACCP Step 4

1 Tasks (from HACCP Step 3 Flow Diagram)	2 Potential hazards identified in HACCP Step 2	3 Are any potential hazards probable? (yes/no)	4 Justify evaluation for column 3	5 What control measures can be applied to prevent undesirable results?	6 Is this task a critical control point? (yes/no)
Task 1	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 2	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 3	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 4	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 5	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 6	Vertebrates				
	Invertebrates				
	Plants				
	Others				

TABLE A1.4 *Continued*

1 Tasks (from HACCP Step 3 Flow Diagram)	2 Potential hazards identified in HACCP Step 2	3 Are any potential hazards probable? (yes/no)	4 Justify evaluation for column 3	5 What control measures can be applied to prevent undesirable results?	6 Is this task a critical control point? (yes/no)
Task 7	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 8	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 9	Vertebrates				
	Invertebrates				
	Plants				
	Others				
Task 10	Vertebrates				
	Invertebrates				
	Plants				
	Others				

TABLE A1.5 HACCP Step 5

HACCP Plan Form (all CCP's or yes's from column 6 of HACCP Step 4–Hazard Analysis Worksheet)								
Critical Control Point (CCP)	Significant Hazard(s)	Limits for each Control Measure	Monitoring				Evaluation & Corrective Action(s) (if needed)	Supporting Documentation (if any)
			What	How	Frequency	Who		
Facility:					Activity:			
Address:								
Signature: HACCP Plan was followed.					Date:			

A2. HACCP-DERIVED DECONTAMINATION PROCEDURES MITIGATING EQUIPMENT-MEDIATED TRANSFERS OF INVASIVE AQUATIC BIOTA, PRINCIPALLY MUSSEL SPECIES

A2.1 Background

A2.1.1 Given the increasing occurrence of dispersal and establishment of invasive species in previously unoccupied terrestrial or aquatic habitats, various organizations have developed procedures which are reflected in this annex intended to provide technical information for managing unintended human-aided dispersal events. See, for example, California Department of Fish and Wildlife 2013 (**39**), Department of Agriculture, Fisheries, and Forestry 2008 (**40**), DiVittorio et al. 2012 (**41**), Jacks et al. 2009 (**42**), Maine Department of Environmental Protection 2008 (**43**), Parsons et al. 2012 (**44**), Stockton et al. 2013 (**45**), Washington State Department of Ecology 2012 (**46**)). For AIS HACCP or principals characteristic of the HACCP process reflected in this standard have served to guide the development of such mitigation practices intended to prevent the spread of AIS such as New Zealand mudsnail (*Potamopyrgus antipodarum*), quagga mussel (*Dreissena rostriformis bugensis*) or zebra mussel (*Dreissena polymorpha*). Typical of all AIS, these invasive mollusa are not easily observed in field settings; hence, unintended transport to new locations on equipment or other materials used in the field serve as potential vectors mediating transfers from occupied habitats to previously unoccupied habitats when equipment or other materials are deployed in areas that are geographically separated, yet potentially linked through management actions mediated by their use. To prevent unintended spread of AIS between field-work locations, procedures for decontaminating equipment and other materials must be implemented to mitigate and reduce risks associated with species transfers linked to use of this equipment or other materials in waterbodies at different locations. Any equipment, including but not limited to wading equipment, dive equipment, sampling equipment such as water quality probes, nets, or substrate samplers, and watercraft must be decontaminated. As an alternative to decontaminating on-site, you may wish to have separate equipment for each site and to decontaminate it all at the end of the day. Procedures listed herein may be used to establish these mitigation practices regardless the decontamination process being completed on-site or at a centralized decontamination area located elsewhere.

Options for equipment decontamination are summarized in this annex. Procedures for decontaminating equipment and other materials should be implemented to mitigate and reduce risks associated with AIS transfers linked to use of this equipment or other materials in waterbodies at different locations. Selection of method(s) appropriate for specific field locations, equipment or work schedule will depend on field settings; past experience (including underlying factors leading to mitigation measures being applied at a given location); their deployment; and future use of field equipment and other materials. Depending on geographic location of mitigation activities, chemical control agents such as molluscicides have not been identified in this guide; chemical control of New Zealand mudsnail, quagga, and zebra mussel diffusely reported in the literature (see for example, Schisler et al. 2008 (**47**), Department of Agriculture, Fisheries, and Forestry 2008 (**40**), Maine Department of Environmental Protection 2008 (**43**), Mackie and Claudi 2009 (**48**), Jacks et al. 2009 (**42**), Britton and Dingman 2011 (**49**), Kiupel et al. 2010 (**50**), DiVittorio et al. 2012 (**41**), Parsons et al. 2012 (**44**), Washington State Department of Ecology 2012 (**46**), Herman 2014 (**51**), Stockton and Moffitt 2013 (**45**), California Department of Fish and Wildlife 2013 (**39**)). As chemical control agents, registered molluscicides are non-selective; hence, their use may be limited because of adverse effects potentially occurring in native species of other species of gastropods and especially the increasing number of species of special-status mussel species recognized in various jurisdictions throughout North America see, for example, US EPA 2006, 2007 (**52, 53**) for chemical control agents frequently deployed; see also http://ecos.fws.gov/tess_public/pub/listedAnimals.jsp last accessed September 30, 2014 for gastropods currently listed as under Endangered Species Act.

A2.2 General field procedures to prevent the spread of AIS (not including disease agents)

A2.2.1 In general decontamination must be completed for all field gear (for example, sampling equipment such as boats, rafts, or other flotation devices; other field apparatus such as sampling devices including seines or other water-sampling or sediment-sampling devices; and personal materials such as waders). If decontamination is not done on site, potentially contaminated equipment should be wrapped and sealed in plastic bags and keep separate from clean gear during transport to a centralized decontamination location. When practical, when working in flowing water work should begin upstream and progress downstream to minimize chances that AIS would be transferred to non-infested upstream areas. For locations with documented infestations with AIS, dedicated equipment used only in infested waters may be appropriate; if so, this equipment must be stored separately from other gear.

A2.3 Decontamination of watercraft, sampling gear and equipment

A2.3.1 *Watercraft decontamination.* Prior to leaving the launch area, remove all plants and mud from your watercraft, trailer, and equipment. Dispose of all decon-generated materials (particularly biological materials) in the trash. segregated for disposal at controlled facilities receiving field waste, such as those identified for disposal of biological waste. Drain all water from your watercraft to receiving areas distant from water sources and characterized by low relief to minimize runoff; dry all areas, including motor, motor cooling system, live wells, bilges, and lower end unit. On return to base

facilities, pressure wash the watercraft and trailer with 60°C (140°F) water (see Note A2.1), including all of the boat equipment (that is, ropes, anchors, etc.) that came into contact with the water. Flush the engine with 140°F water for at least 10 minutes and run 140°F water through the live wells, bilges, and all other areas that could contain water.

NOTE A2.1—To ensure 100% mortality water temperature should be no less than 68°C (155°F) at the nozzle to assure 60°C (140°F) at the point of contact.

A2.3.2 *Sampling gear and equipment.* Three options are considered acceptable and are intended to benefit field operations occurring under differing environmental conditions that might influence how decontamination occurs. These options may be implemented jointly as time allows; for example, if more than one location will be sampled during a given work period, then dry-scrub decontamination may be implemented following sampling event at a first location, then a hot-water scrub and soak might be implemented when sampling is completed for the day.

A2.3.2.1 *Dry scrub.* Scrub gear with a stiff-bristled brush to remove all organisms with particular attention given to small crevices such as boot laces and seams, wader attachment points, corners of nets and tie-offs of seines, or similar joints in hardware connectors. Allow equipment to dry until any moisture is completely dissipated; exposure to sunlight during the process assures drying and limited disinfection via UV exposure. Keep dry for a minimum of 48 hours to ensure any organisms are desiccated.

A2.3.2.2 *Hot water scrub and soak.* As in A2.3.2.1 scrub gear with a stiff-bristled brush to remove all organisms with particular attention to small crevices such as those in seams and other join points in fabrics and materials. After that through scrubbing, immerse equipment in 60°C (140° F) or hotter water. Assure that the entire piece of gear or equipment is submerged; weigh down the object to ensure it remains immersed for no less than five minutes.

A2.3.2.3 *Water scrub and freeze.* As in A2.3.2.1 scrub gear with a stiff-bristled brush to remove all organisms with particular attention to small crevices such as those in seams and other join points in fabrics and materials. After that thorough scrubbing, place gear or equipment in a freezer 0°C (32°F) or colder for a minimum of eight hours.

A2.3.3 *Field identification of invasive mussels.* Current web-based identification guides are available (see, for example,

http://nas.er.usgs.gov/default.aspx or http://www.invasivespeciesinfo.gov/aquatics/main.shtml (last accessed September 30, 2014)

and complement earlier technical publications (see Claudi and Mackie 1994 (**48**) updated by Mackie and Claudi 2009 (**54**), see also Nalepa and Schloesser 2013 (**55**)) focused on identification of these mussels on equipment or other materials. Field-ready identification guides may be assembled prior to implementing field sampling efforts to expedite identification of AIS common to the region.

A3. HACCP-DERIVED DECONTAMINATION PROCEDURES FOR CONTROLLING EQUIPMENT-MEDIATED TRANSFERS OF DISEASE AGENTS OF AQUATIC BIOTA, PRINCIPALLY INFECTIOUS AMPHIBIAN DISEASES IN FRESHWATER HABITATS

A3.1 Background

A3.1.1 Pathogens can be transferred between and among different locations within aquatic systems—lentic or lotic. Hence, a wide range of disease agents are capable of entering previously unoccupied habitats through actions of biological vectors or other transfer agents that assure their potential passage through numerous pathways See below:

http://www.fws.gov/answest/Docs/WRP%20Guidance%20for%20Field%20Gear%2018%20Nov%202012-1.pdf (last accessed June 18, 2014)

In the wild and in absence of human intervention, little direct control can be exerted over most of these pathways where waterfowl or shore birds, other migratory birds, foraging ungulates and other wildlife such as beavers may be critical components in completed pathways. In general transfers of disease agents may be enabled when these disease-specific biological vectors serve as mediating agents; hence, vectors for a wide array of pathogenic microorganisms are many, yet common attributes of biological or physical transfer agents benefit development of countermeasures that potentially mitigate transfers by interrupting pathways at critical controls points (CCPs) in the chain-of-events required for successful species invasions or transfers of disease agents from one area to another, oftentimes previously unoccupied area. This annex focuses on a disease agent of amphibians—chytrid fungus, *Batrachochytrium dendrobatidis*—which calls for countermeasures (see Johnson et al. 2003 (**56**)) that would also mitigate disease agent transfers coincident with management of other aquatic biota practices, including aquaculture; see, for example,

http://www.fs.usda.gov/detail/r4/landmanagement/resourcemanagement/?cid=stelprdb5373570

Sadler and Goodwin 2007 (**57**), Scarfe et al. 2006 (**58**),

http://www.fs.usda.gov/detail/r4/landmanagement/ resourcemanagement/?cid=stelprdb5373570 (last accessed June 20, 2014)

A3.2 *Mitigating transfers of disease agents of amphibians through decontamination of field gear and equipment.*Disease agents of amphibians have increasingly been encountered in the field, most recently for chytridiomycosis which increased awareness of disease threats to fish and wildlife potentially linked to declining populations of susceptible species (see, for example, Daszak et al. 1999 (**59**); Friend 2006 (**60**); Wilcox and Gubler 2005 (**61**); Ostfeld et al. 2008 (**62**)). As contributing factors to continuing amphibian declines in worldwide populations and diversity, these disease agents are problematic

during field activities that potentially turn inadvertent encounters with humans into initiating events in a species transfer process McLean 2007 (**63**); Mörner et al. 2002 (**64**); Phillott et al. 2010(**65**); Green et al. 2009 (**66**); Densmore and Green 2007 (**67**); see

http://www.pwrc.usgs.gov/nearmi/disease/ or
http://www.amphibiaweb.org/declines/ diseases.html (last accessed June 18, 2014)

This annex is derived from CCPs identified during a HACCP evaluation process and specifies countermeasures that serve as mitigating factors intended to offset risks associated with in-field activities regardless those activities being directly related to disease investigations (Pessier and Mendelson 2010 (**68**); Mörner et al. 2002 (**64**); see also Chapter 4, http://www.nwhc.usgs.gov/publications/field_manual/ last accessed June 20, 2014) or routine operations involving ingress and egress from areas where disease occurs in fish or wildlife within a specific region (see, for example, Sadler and Goodwin 2007 (**57**), Parsons et al 2012 (**44**)available at

http://www.ecy.wa.gov/programs/ eap/qa/docs/ ECY_EAP_SOP_MinimizeSpreadOfAIS_v2_0EAP070.pdf (last accessed June 12, 2014)

Wobeser 2002 (**69**), Restif et al. 2012 (**70**)).

In the field the level of infection control cannot duplicate that achieved in controlled settings such as that in an aquaculture facility or amphibian vivarium (Scarfe et al. 2006 (**58**), Poole and Grow 2012 (**71**)). Yet, standard guidance can offer practical field-implemented procedures that are intended to ensure field investigators do not serve as agents to spread disease or otherwise act as vectors increasing the risk of disease outbreaks in previously unoccupied areas by transporting pathogenic agents between individual work venues. Remember that outcomes of a disease outbreak are predicated on successful initial contacts between disease agents and susceptible hosts and establishment of transmission connections between other susceptible hosts. Each step in the "susceptible-infected" process is highly dependent on the number of infectious particles contained in the transfer inoculant (Grassly and Fraser 2008 (**72**)). Whereas the steps outlined in this guide may not kill all infectious agents or propagules on field gear or other equipment, a reduction in the number of infectious agents or propagules provided chances to invade, become established in previously unoccupied areas, and encounter susceptible amphibian hosts will reduce the probabilities of infection occurring and increased occurrence of disease occurring. Guidance herein assumes that specialized equipment such as field-dedicated disinfection and sterilization equipment such as hot-water pressurized sprayers are not available or may not be available for deployment at remote locations.

A3.2.1 *Planning for decontamination activity in the field.* Regardless the number of people serving as part of the field crew, the key element of successful decontamination operations ("decon") is planning before field work is undertaken. Although not encouraged from an occupational health and safety standpoint, for example, USGS 2014 (**73**), Bureau of Land Management 2001 (**74**), Gochfeld et al. 2006 (**75**), Lane et al. 1997 (**76**), Oliveri et al. 2005 (**77**)), if an individual is working by themselves in field settings, planning becomes even more critical to your successful field operations and subsequent decon. Regardless the number of participants in field deployments, performance criteria shaping development of this guide are few, namely, effective decontamination of field gear and equipment before leaving any field site.

A3.3 Basic supplies and materials

A3.3.1 Minimum required supplies and materials are listed as indicated; depending on field setting and past experience gained by field crews, the list of supplies and materials may include items that are not listed and considered in this guide, yet have demonstrated past benefits for deployment in the field decontamination, depending on specific operational settings (for example, decon completed at an air-support base during wildfire operations will differ markedly from decon activities completed by a small field crew working in remote area.)

A3.3.2 Plastic tarpaulin (8-ft × 8-ft or larger; additional tarpaulins as needed)

A3.3.3 Granulated chlorine or alternative disinfection chemical(s)

A3.3.4 Water container(s) for dipping or washing field gear, equipment, or other materials

A3.3.5 Hard-bristle scrub brushes

A3.3.6 Plastic laboratory apron(s)

A3.3.7 Long-sleeved wash gloves

A3.3.8 One-gallon (~3.8L) jugs or buckets (collapsible or nesting, if available; 3 or more)

A3.3.9 Extra change(s) of clothes for members of field crew

A3.3.10 Stowage bags for decontamination supplies and materials

A3.4 Decontamination of field gear and equipment required for completing field work

A3.4.1 As noted previously, working alone in the field is not encouraged; hence, procedures discussed in this guide assume field operations are completed with at least two members of a field crew tasked for these operations. For this guide we are focused on freshwater habitats, particularly those activities involved with studies focused on amphibians. Other aquatic biota might also be linked to studies concerned with disease agents such as those specific to amphibians, and if so, procedures provided herein may require modification to address, for example, differences in disease agent attributes that influence disinfection processes considered in the decontamination procedures.

A3.4.2 Field activities should begin with previously decontaminated equipment; sterilization is likely not indicated for most field gear and equipment, but all materials must have been decontaminated prior to entry into an area known or suspected as being habitat occupied by disease agents of concern to the field sampling efforts. Pre-entry decontamination may be completed using a 5% to 6% bleach solution; thus, all equipment such as dip nets, two-pole seines, hip boots, or chest waders, should be ready for use upon arrival at the field-work location. Alternative decontamination chemicals

might include but are not limited to didecyldimethyl ammonium chloride (1-2% solution or 10-20 ml/liter disinfectant solution; see also,

http://householdproducts.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=963 (last accessed June 15, 2014)

or other disinfection products. For example, Bryan et al (2009) (**78**) reported that 3% household bleach (active ingredient [AI]: sodium hypochlorite at 5.25-6.15%; Centers for Disease Control and Prevention, http://www.cdc.gov/ hicpac/disinfection_sterilization/6_0disinfection.html#a2), 0.75% Nolvasan® (Fort Dodge Animal Health; AI = chlorhexidine diacetate) or 1% Virkon® S (DuPont Animal Health Solutions; AI = potassium peroxymonosulfate) solutions were effective for inactivating ranaviruses. Similarly, regional teams within US Forest Service have collaboratively developed decontamination guidance that focuses on issues regarding the unintentional transfer of various invasive species or disease agents as a consequence of wildfire management practices potentially serving to complete biota transfer pathways from occupied to previously unoccupied areas (Table A3.1). Table A3.1 also illustrates the potential for harmonization of decontamination procedures provided the sensitivity of disease agents co-occurring in a management area are sufficiently similar to be amenable to common decon practices. For example, causative agents of chytridmycosis and whirling disease, *Batrachochytrium dendrobatidis* and *Myxobolus cerebralis*, respectively, may be jointly managed by implementing the same decontamination procedure determined on a case-by-case basis, depending on their occurrence in an area of management concern. Decontamination practices may benefit from early implementation of HACCP and characterization of CCPs that may be similar across a range of species life histories wherein different disease agents may be limited with respect to their transfer potentials by using, for example, sodium hypochlorite concentrations for contact periods sufficient to achieve decontamination for each disease agent. Leveraging similarities in life-history attributes to achieve decontamination sufficient to offset risks of disease-agent transfers would benefit field activities focused on routine resource management practices (for example, monitoring for occurrence of malformations in amphibians) or active disease-occurrence investigations actively tracking suspect area where previous occurrence has been recorded.

A3.4.3 In addition to sampling gear and other equipment such as instruments and any supplies or materials not destined for disposal by incineration, vehicles such as trucks, pickups, or automobiles have been identified as abiotic vectors enabling the spread of animal and plant diseases (and also serve as means for transport of invasive species). For example, in veterinary practices, diseases of livestock and wildlife have been linked to transport of disease agents by way of vehicular transport mechanisms between ranches and farms. Centers for Disease Control and Prevention 2011 (**81**), LeBlanc et al. 2006 (**82**), Noordhuizen and Welpelo 1996 (**6**), Kruse et al. 2004 (**83**)). Thorough cleaning of field vehicles is routinely practiced by veterinary professionals and field investigators traveling among animals populations potentially vulnerable to disease agents capable of being transported between work venues, for example, infective propagules of disease agents linked to livestock at one location may have infective stages of an undiagnosed disease. Wildlife populations are vulnerable to disease as well; therefore, for field biologists, scrubbing down the tires on the field vehicle may be a necessary practice, especially if vehicle has been driven through a stream or creek or nearby habitats.

A3.4.4 In lentic (pond) and wetland habitats work should progress from presumptively unoccupied locations to suspect locations, with the latter being those that are known to be or suspected of being occupied by disease agents or vectors; hence, increased likelihood of initiating a transfer event. Prior to entering any area where field work is anticipated, determine if there have been disease occurrence data recorded in the area and plan your work flow. Sampling venues should be arranged to minimize opportunities to inadvertently transfer disease agents or their vectors from occupied to unoccupied habitats.

A3.4.5 Similar precautions with field activities should be implemented in lotic (stream) habitats. Surveys or similar field activities should begin in areas considered unoccupied by disease agents or their vectors. Depending on initial characterizations of field conditions, work in lotic habitats may typically progress from upstream locations characterized as having no disease occurrence to downstream areas where disease occurrence has been recorded or disease agents are suspected to occur. If field activities unavoidably find work flow moving from areas where disease records indicate presence of disease agents or their vectors, and work flows require moving from these known-occurrence venues to presumptively disease-free areas, then decontamination may be necessary at various locations within the work area, for example, if work flow moves from downstream-diseased areas to upstream areas considered ‘disease-free’, then decontamination should be completed before proceeding to an upstream work site.

A3.4.6 If records of disease occurrence in a particular work venue are not available, but within-region records indicate that occurrence of a disease or disease agent has been recorded, then precaution should be taken in completing field activities potentially initiating transfer events. Few places have been surveyed for the presence of disease agents or occurrence of disease; hence, decontamination procedures may be implemented at the discretion of the field crew-chief to mitigate unintentional transfer events.

A3.4.7 Regardless the aquatic habitat—lotic, lentic, or wetland—decontamination of all vehicles, equipment, field gear, or clothing of field-crew members between each work venue should be completed regardless the status of a wider-ranging resource management area, such as a wildlife refuge where field work is being completed at various locations within management units. Distribution of disease occurrence records within such a wider-ranging resource management area are likely not complete and inadequate to a quantitative characterization of disease prevalence or incidence. See Note A3.1.

NOTE A3.1—Whereas many endpoints related to disease occurrence and frequency have been defined in literature, disease ecologists or public-health epidemiologists most often estimate the occurrence of disease in a population in terms of incidence or prevalence. The primary

TABLE A3.1 Comparision of Disinfection Regimen for Field Gear and Equipment Potentially Contaminated with Disease Agents Causing Whirling Disease of Chytridmycosis

Disease agent	Wash and scrub[A]	Temperature °C (°F)	Drying	Bleach (5-6% sodium hypochlorite; [NaClO])	Quaternary ammonium chemicals[B]	References
Whirling Disease	yes	90°C (195°F) for at least 10 min	Best if dried 24 h in sunlight (UV disinfection)	For 10 min: 1% bleach solution (500 mg NaClO/L disinfecting solution)	For 10-15 minutes: (1500 mg quaternary compound/L disinfecting solution)	Hedrick et al. 2008 (79) Wagner 2002 (80)
				• 1.1 oz liquid bleach per gallon water	Using 4.4% Quaternary ammonium compounds solution[C]	
				• 2.2 Tbsp liquid bleach per gallon water	• 6.1 oz Quaternary ammonium compounds solution[C] per gallon water	
				• 0.9 Gallons bleach per 100 gallons water	•4.8 Gallons Quaternary ammonium compounds solution[C] per 100 gallons water	
					OR	
					Using 3 % Quaternary ammonium compounds solution[D] solution (12.5% quaternary compounds)	
					4.1 oz Quaternary ammonium compounds solution[D] per gallon water	
					•3.2 Gallons Quaternary ammonium compounds solution[D] per 100 gallons water	
					OR	
					Using 1.7% Quaternary ammonium compounds solution[E]	
					•2.4 oz Quaternary ammonium compounds solution[E] per gallon water	
					•1.9 Gallons Quaternary ammonium compounds solution[E] per 100 gallons water	
Chytrid Fungus	Yes	60°C (140°F) for at least 5 minutes	Best if dried at least 3 hours in sunlight (UV disinfection)	For 30 sec: 20% bleach solution (>1% NaClO)	For 30 sec:	
				•22 oz liquid bleach per gallon water	Using 0.015% Quaternary ammonium compounds solution[C]	
				•17 Gallons bleach per 100 gallons water	• 0.02 oz Quaternary ammonium compounds solution[C] per gallon water	
				For 10 min: 7% bleach solution (0.4% NaClO)	• 0.6 ml Quaternary ammonium compounds solution[C] per gallon water	
				• 9 oz liquid bleach per gallon water	• 1/8 tsp Quaternary ammonium compounds solution[C] per gallon water	
				• 7 Gallons liquid bleach per 100 gallons water	OR	
					Using 0.04% Quaternary ammonium compounds solution[D]	
					• 0.06 oz Quaternary ammonium compounds solution[D] per gallon water	
					•1.8 ml Quaternary ammonium compounds solution[D] per gallon water	
					• 0.36 tsp Quaternary ammonium compounds solution[D] per gallon water	Johnson et al 2003 (56)
					OR	
					Using 0.01% Quaternary ammonium compounds solution[E]	
					• 0.03 oz Quaternary ammonium compounds solution[E] per gallon water	
					• 1.0 ml Quaternary ammonium compounds solution[E] per gallon water	
					• 0.2 tsp Quaternary ammonium compounds solution[E] per gallon water	

[A] Remove mud and inorganic materials, vegetation and other organic detritus.
[B] Such as, alkyl dimethyl benzylammonium chloride [ADBAC] or diecyl dimethyl ammonium chloride [DDAC]).
[C] Alkyl (C14- 50%, C12-40%, C16-10%, dimethyl benzyl ammonium chloride); 5.000 %
Octyl decyl dimethyl ammonium chloride; 3.750 %
Dioctyl dimethyl ammonium chloride; 1.875 %
Didecyl dimethyl ammonium chloride; 1.875 %
[D] Octyl decyl dimethyl ammonium chloride; 6.510%
Dioctyl dimethyl ammonium chloride; 3.255%
Didecyl dimethyl ammonium chloride; 3.255%
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride; 8.680%
[E] Didecyl dimethyl ammonium chloride; 5.07%
n-Alkyl (C14 50%, C12 40%, C16 10%) dimethyl benzyl ammonium chloride; 3.38%

difference between these terms is related to time of disease onset. Incidence focuses on counts of previously unrecorded disease occurrence or outcomes of exposure (“new cases” or “new reports”); prevalence summarizes count data for previously unrecorded disease occurrence

("new reports") and existing cases of the disease or outcomes of exposure.

Heterogeneity in spatial and temporal distribution data more often than not precludes reliable estimates of locations of disease agents or their vectors within any specific habitat setting. Surveillance activities monitoring disease incidence are likely similar in their being inadequate to characterize disease 'found-not found' data within a quantitative characterization of disease prevalence. Just as habitat heterogeneity and empirical data collections, such as those garnered from wildlife population studies, critically affect technical and management practices for estimating animal populations, characterizing disease occurrence based on, for example, presence-absence data collected haphazardly consequent to incident-driven observational studies does not necessarily imply that all vulnerable habitats within a widely-ranging management area may have or may not have disease agents present. Decontamination procedures address these uncertainties with the intent of erring on the side of caution.

A3.5 Background on Decontamination Activities

A3.5.1 This annex is predicated on preparation of a field study plan or field activity plan wherein locations of work-related survey or sampling will be identified and work plans completed. Such planning activity would benefit from implementation of a HACCP-based planning process wherein a field-level analysis of hazards included identification of sampling equipment and materials required of the work, and activities related to pre-deployment decontamination of equipment and materials prior to mobilization. At a minimum those decontamination supplies and materials identified in A3.3 should assembled; alternative disinfection materials such as quaternary ammonium chemicals (see Table A3.1) or other chemicals US EPA 2006, 2007 (**52, 53**); see also Scarfe et al. 2006 (**58**), Schisler et al. 2008 (**47**)) may be substituted for granular chlorine, if equivalent disinfection efficiencies are assured by using those alternatives and their use in the field is preferred by field crew chief.

A3.5.2 *Decontamination setup and procedure.* Although field settings will determine how decontamination is accomplished, stepwise procedures provided in this standard guide should assure that the process is accomplished regardless the place of operations. (see Annex A2 for decontamination procedures potentially modified to address concerns related to disease agents of amphibians; see also USGS 2009, Centers for Disease Control and Prevention 2011(**81**) for general guidance). Segregation of field activities into areas where *(1)* no direct interactions with disease agents or vectors are likely to occur (staging area), *(2)* transition area(s) delineated as "buffer zone(s)" which separate staging area from *(3)* area(s) of concern (AOC; "infected area") wherein disease occurrence has been documented or disease agents have been isolated in previous investigations. Scale of spatial segregation depends on extent of disease occurrence, area of concern, disease agent, and field setting, including sampling venues interconnectedness to surrounding area. By using field-level hazard analysis and identifying critical control points as outcomes of exploratory HACCP evaluations, field operations can be implemented with reduce opportunities for work-related events likely to promote dispersal of disease agents, vectors, or abiotic materials that might contribute to dispersal of disease agent. Depending on life history of disease agents, habitats, and biota being surveyed, decontamination may occur at various locations, for example, near docksides supporting operations involving boats or inflatables or immediately adjacent to wetlands or emergent zones of lotic habitats where disease occurrence has been recorded or is suspected to occur. As illustrated in Fig. A3.1, access to AOC is controlled to reduce opportunities for investigation-related dispersal events either through direct involvement of field crew or indirectly through unintended dispersal events linked to activities involved with the investigation. Depending on the scale of the investigation, a command post (CP) located in the staging area *(1)* provides field-staff a rally point for deployment and reassembly as field activities progress to completion, whereas in larger field operations CP houses administrative staff and provides for field-staff support (for example, break area, dining, first aid, materials and supplies). Logistics are served by *(2)* parking and temporary storage area(s), which also vary in their level of development depending on scale of investigation. Multiple locations may be required for *(3)* decontamination ("decon") pads; their numbers may be few—frequently only a single venue in many field operations—or many for AOCs that include many sampling venues occurring over a relatively widespread spatial extent. Many decon pads may be required in AOCs involving two or more, closely located sampling locations as depicted in Fig. A3.1, wherein wetlands of emergent zones were deemed best served by decon pads separate from those dock-side decon pads that served open-water areas of the ponds. Regardless the scale of field operations involved in any particular investigation's location, work flows from staging area to AOC via transition area involve work activities that are scale-independent and largely determined by field-crew chief or incident commander.

A3.5.3 *Task Assignments for Field-Crew Members.* In the field individual members of the crew should be designated as either "support crew" or "exposed crew." Exposed crew members will be primary for entering areas previously identified in the planning process "as likely to harbor disease agents or their vectors." For example, in wetland habitats members of the exposed crew would enter the water for sampling or have other direct contact with physical habitat and biota being sampled as part of survey or monitoring operations. Equipment used by or gear being worn by exposed crew members would be considered presumptively contaminated and require decontamination, whereas members of support crew and their equipment or gear would be less likely to require decontamination provided field operations were nominal and no incidents occurred that potentially lead to completed pathways linking disease agents to equipment or gear of exposed crew. In-field decisions regarding decontamination or disposal of equipment, gear, or materials is the prerogative of field-crew chief. As prior planning would have identified, see, for example, California Department of Fish and Wildlife 2013 (**39**), Department of Agriculture, Fisheries, and Forestry 2008 (**40**), Gochfeld et al 2006 (**75**), Jacks et al 2009 (**42**), Parsons et al. 2012 (**44**)), by compartmentalizing field activities and assigning crew

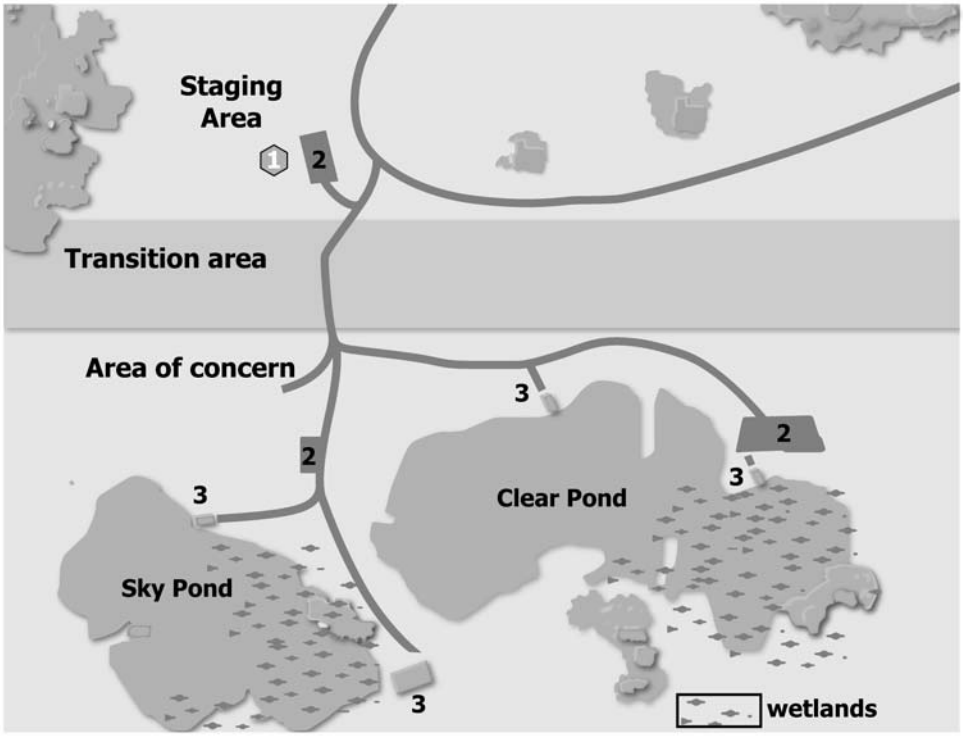

FIG. A3.1 Illustrative example of field investigation involved with, for example, disease monitoring and surveillance activities following discovery of chytrid infection in resident amphibians in emergent wetlands of Sky Pond and Clear Pond. Key areas or zones within any investigation or study venue: *(1)* Command post to provide field-staff support or in larger field operations houses administrative staff and provides for field-staff support (for example, break area, dining, first aid, materials and supplies); *(2)* parking and temporary storage; *(3)* decontamination pad (modified from USGS 1999– Friend, 1999 (84)).

members specific tasks required of field sampling, exposed crew members would limit their activities within their containment boundaries, then pass sampled materials to member(s) of support crew. Members of the support crew would usually not need to enter the waters or muddy areas of AOC (for example, emergent zones), provided sampling was being completed by exposed crew operating in lotic, lentic, or wetland habitats. Depending on field setting, the boundaries of containment could effectively be maintained by having exposed crew work with buckets or small inflatable work platforms to haul or provide temporary stowage of materials or container with sampled biota or other abiotic substrates; if biological samples were intended as 'live captures', then buckets or other suitable containers filled with water from sampled location could be positioned near the boundary between exposed area from support area prior to sample processing (Fig. A3.1).

A3.5.4 The activities being completed by exposed and support crews are mediated by way of an exchange zone within the AOC wherein members of exposed crew hands off sampled materials to support crew. In sampling venues that require only a small field crew of 2 to 4 members, distinct lines between tasks completed by exposed crew and support crew may be blurred, yet clearly fitting within the context of a 'dynamic boundary' between exposed crew and support crew. For example, for work focused on amphibian diseases considered primary in this annex, support crew would set up decon pads that consist of tarpaulins laid and staked at specific locations linked to exposed crew's points of ingress and egress from an emergent zone being samples. That tarpaulin might be repositioned throughout a day's field activities, depending on the specific venues being sampled by exposed crew; hence, the hand off of biota or other materials sampled would occur in an exchange zone that potentially moved throughout the sampling event. Regardless, the tarpaulin remaining at a fix location throughout the day or its location moving from one venue to another to ease exposed crew's work effort, the tarpaulin would delineate a "clean" work area. Any equipment (spring scales, measuring rules, dissection equipment, etc.) used for sampling amphibians would be restricted to area covered by the tarpaulin. Depending on the level of sample preparation completed by the support crew, additional institutional controls might also be included such as protective plastic aprons to protect clothing from getting wet or soiled consequent to completion of their sample processing tasks or photodocumentation of, for example, biological specimens. As such the support crew would occupy the area bounded by the tarpaulin throughout their interactions with exposed crew; hence, one CCP would be that exchange zone delineated by the tarpaulin. Tasks being completed thereon such as transfer of sampling materials from support crew to exposed crew (for example, clean sample containers, field equipment or other materials) in exchange for biota or other materials sampled by the exposed crew (for example, properly labelled sample containers, waste materials

requiring post-sample processing and disposal) would be contained within the context of sampling-related hazards.

A3.5.5 Disinfection solutions should be prepared in water containers (for example, collapsible basins or nesting in form such as nested dish pans) and positioned on the tarpaulin to assure work-flow of support crew can proceed unimpeded. Once tarpaulin work area is established, tasks assigned to support crew and exposed crew effectively exclude each crew from the other crew's area of operations unless otherwise required as directed by crew-chief. Once members of the exposed crew enter the area being samples (for example, wetlands, emergent zones of lotic or lentic habitats), they should remain off the tarpaulin-delineated work area until their sampling tasks are complete and all sample-related tasks assigned to support crew, such as cataloging and preparing samples for shipment, are completed. Once sampling tasks are completed by support crew, the tarpaulin subsequently supports decontamination activities for exposed crew wherein field gear (for example, waders, rubber gloves) or equipment (for example, dip nets, seines) are cleaned and prepared for the next field sampling effort.

A3.5.6 Depending on disinfection chemicals of choice (see, for example, Table A3.1; see, for example, Schisler et al. 2008 (**47**) for other disinfectant chemicals potentially applicable to field disinfection procedures), in-field preparation of disinfection stations should be completed within containment area delineated by tarpaulin. For this annex we focus on granulated chlorine (commonly available as Calcium Hypochlorite ($CaCl_2O_2$)/Sodium Hypochlorite (NaOCl) CAS 7778-54-3/7681-52-9; UN 1748/1791; see Center for Disease Control and Prevention circular available at http://www.atsdr.cdc.gov/MMG/MMG.asp?id=927&tid=192 last accessed June 15, 2014), given its ease in transport to either remote or support base facilities supported by dedicated equipment at fixed decontamination venues. Regardless of remote or fixed venues, granulated chlorine should be stored and transported in a puncture-proof container; hence, the quantity carried in the field may vary and depends on the number of field locations being visited during any given period from base supply. In its granulated form chlorine has the advantage of more portable than liquid bleach, which tends to lose effectiveness once opened. Depending on mobilization requirements demanded by field locations (for example, remoteness from base supply), transport and storage of granulated material should assure that exposure of dry-chlorine product to water does not occur until decontamination activities are initiated in the field. Ideally, dry product is pre-measured and stored under anhydrous conditions until needed. For example, based on solution strength required to achieve disinfection (Table A3.1), chlorine granules might be pre-measured into double seal-able plastic bags which are then evacuated of air to reduce exposure of materials to moisture. These bagged aliquots of granulated material could then be stored in puncture-resistant containers prior to deployment in the field.

A3.5.7 Once decontamination area is established, exposed crew and support crew proceed with their previously assigned work tasks. Exposed crew will initiate and continue sampling by, for example, seining and/or dipnetting for amphibians in studies focused on infectious diseases of these animals. Animals captured and selected for examination will be taken to support crew tarpaulin-delineated work area after being held in temporary confinement in, for example, sample buckets or other containers capable of holding site-water. Site-water collected in these transport/temporary holding containers will be returned to ponds once sampling of animals is complete. Other biological samples may be collected by exposed crew to address study-related questions related to vectors or co-occurring biota of interest to the resource managers charged with assessment, monitoring, and surveillance activities. Abiotic samples, such as surface waters, sediments, or hydric soils, may also be collected by exposed crew to satisfy collection requirements detailed in the study plan developed for the project. Regardless the nature of the samples collected by exposed crew from habitats occurring within AOC(s), clear lines of separation should remain in place between exposed and support crews, with hand-offs between these study compartments occurring at the limits of the delineated decontamination area.

A3.5.8 Depending on the type of samples collected by the exposed crew and delivered to the support crew at their work area on the tarpaulin-delineated decontamination area, members of support crew should follow prescribed disinfection procedures as necessary, including the use of plastic aprons or other materials serving as coveralls and gloves, if required by sampling procedures. For example, when working with animals collected from exposed areas, support crew should disinfect their hands and forearms after handling each animal, then rinse thoroughly before handling the next animal. See Note A3.2.

NOTE A3.2—See CDC guidance on hand and skin care when using hypochlorite-based disinfection chemicals at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a.htm (last accessed June 19, 2014).

A separate hand disinfection and rinsing station should be set up, if animals are to be handled, then returned (for example, as part of a mark-recapture study design). As indicated by previously developed sample processing procedures supported by process detailed in this annex, pond water may be acceptable for rinsing, if no other water source is available. For capture-release operations, surgical gloves (latex or non-latex, as specified in study plans) may not be recommended, because of sensitivity of amphibian skin. Specific handling procedures should be established prior to field operations and are not considered in this standard guide. Similarly, specific procedures for handling abiotic materials such as sediments are not specified herein, but other ASTM standard guides are available to specify procedures supporting support crew actions regarding bookkeeping and sample processing (see ASTM E1391-03 (2008), Standard Guide for Collection, Storage, Characterization, and Manipulation of Sediments for Toxicological Testing and for Selection of Samplers Used to Collect Benthic Invertebrates or US EPA 2001 (**85**)).

A3.5.9 Throughout field sampling and sample processing, do not allow disinfectants to contact amphibians, particularly when mark-recapture studies are in play. If this guide intends to serve other sampling programs focused on other biota, then

similar cautions are likely in order but must be considered on a study-by-study basis.

A3.5.10 For diseases of fish and wildlife having no record of transmission of zoonotic diseases, decontamination focuses on reducing, if not eliminating, potential for field gear and sampling equipment from facilitating transfers of disease agents from the area just sampled to those AOCs yet to be visited. Upon completion of field sampling activities for any location or for any period of time (for example, end of work period), all field gear and equipment must be decontaminated before leaving the sampling venue. To initiate decontamination procedures support crew should prepare their tarpaulin-defined work area to accommodate decontamination activities, then aid exposed crew in their decontamination process. Thorough decontamination for disease agents of amphibians such as chytrid fungus or ranavirus requires washing and scrubbing surfaces of sampling gear and equipment using long-handled, hard-bristled scrub brushes until vegetation, other biota and detritus is removed, then disinfection using hypochlorite or other disinfectant solutions (see Black and Veatch Corporation 2010 (**86**) for details on disinfection). Regardless the disinfection chemical deployed in the field, contact time between surfaces and disinfectant is critical to achieving high disinfection efficiencies ASTM 2013a (**87**)); once washing to remove mud and other environmental materials is accomplished, disinfection process should be completed no less than 3 minutes or other contact period sufficient to attain disinfection (ASTM 2013b,c (**88, 89**)). If sample processing has proceeded uneventfully, support crew decontamination should be relatively limited, most commonly involving washing of hands and forearms disinfectant soap to assure in-field exposure to disease agents linked to amphibian diseases are killed by disinfection chemicals. Following disinfectant wash and rinse, support crew should then assist exposed crew in their decontamination process, for example, disinfection of field gear and equipment, while exposed crew focuses on cleaning of clothing and personal gear such as waders. Once support crew is complete with decontamination of field gear and equipment, and exposed crew has completed decontamination of clothing and personal gear, a final wash of hands and forearms with disinfectant soap and final rinse completes the decontamination process.

A3.5.11 Clean up after washing and disinfection may be simplified, if containment of rinse materials is accomplished using, for example, collapsible basins or similar containers. Final steps in decontamination process should include rinse and soak of tarpaulin, plastic aprons, any buckets or collapsible containers, and scrub brushes for no less than 3 minutes. Once decontamination of these materials is complete they should be air-dried and exposed to sunlight to promote UV disinfection. Air-drying and UV exposure may be completed as part of demobilization, following a day's work, if support facilities are available. If exposed crew or support crew had their clothing get wet or soiled with mud or other abiotic material in completing sampling activities, clothing should be changed and stored temporarily in plastic bags for cleaning at support facilities. Field personnel should be alternately assigned to support or exposed crews to assure all field-crew members are experienced with tasks required of each team.

A3.6 Disposal of disinfecting chlorine or other disinfectant solutions in a field setting must be completed safely, with particular concerns focused on chlorine toxicity to aquatic biota occupying habitats likely subject to such disease investigations. This guide specifically considered chlorine disinfection because of its long history in field research focused on disease-agents and their roles in ecology and public health. Black and Veatch 2010 (**86**); see also http://www.cdc.gov/healthywater/drinking/history.html last accessed September 30, 2014.). Hence, these measures are based on disposal of aqueous chlorine solutions originally prepared from commercially available bleach or anhydrous chlorine salts, the latter specified herein as a disinfectant of choice. Given amphibians and disease agents of amphibians are priority drivers of this guide, and given the toxicological properties of chlorine for aquatic biota, as early characterized by Larson et al (1978) (**90**) and as subsequently characterized by US EPA (1984) (**91**); see also,

http://water.epa.gov/scitech/ swguidance/ standards/upload/2001_10_12_criteria_ambientwqc_chlorine1984.pdf and http://www.env.gov.bc.ca/wat/wq/BCguidelines/chlorine/chlorine.html#toc (last accessed September 30, 2014),

a primary concern in the disposal of chlorine-based disinfectant solutions is proximity of disposal site to aquatic habitats. Whereas hypochlorites have a wide spectrum of activity and are among the most commonly used disinfectant solutions, their primary disadvantages are *(1)* organic matter readily inactivates them and *(2)* working solutions tend to decompose quickly. However, both these disadvantages in their role as disinfectant benefits disposal of solutions in the field. Provided discretion is practiced with respect to volumes of disinfectant solutions generated from field activities, and quantities of unused and waste solutions are small, disposal of hypochlorite solutions in the field may be accomplished by releasing liquids to soils wherein interaction with organic matter promotes inactivation or releases to surfaces favoring photoinactivation (for example, spreading liquid over a relatively impervious surface such as hardened parking lot to promote photoinactivation). Regardless the location of the surface release, disposal must be completed a safe distance from any water body, be that lake or pond, river or stream or creek, or wetland. Safe venues for disposal might be specified based on distance from vulnerable habitats and relative differences in elevation between vulnerable habitats and release site (for example, widely separated disposal and vulnerable areas with small difference in elevation between them would be best), organic content of soils, and permeability of soils or near-surface substrates (including parking lots and unpaved roads); see, for example, State of Oregon Department of Environmental Quality 2012 (**92**), Tikkanen et al 2001 (**93**)).

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