University of Notre Dame
Laboratory Integrated Safety Plan (ISP)

I. Executive Summary

The overarching goal of the Laboratory ISP is to create a culture of safety at the University of Notre Dame. The ISP creates a structure for managing safety and health at a local level with the benefit of the Risk Management and Safety (RMS) Department as a resource. Further, the Laboratory ISP is a means to coordinate and promote practices that mitigate risk associated with hazards present in laboratory environments.

There are three basic aspects to the ISP:

1. Individuals hold responsibility for their own safety and that of their co-workers.

2. All laboratories must undergo safety evaluation and all laboratories determined by RMS to be housing significant safety risks must be safety validated.

3. All laboratories are guided in their efforts to maintain a safe environment by both RMS and a Local Safety Committee (LSC). In this regard, LSCs are to be organized around a College, Department, Center, Institute, or other unit having a well-defined administrative lineage that progresses to a Dean, Department Head, or to the Provost. The specific level at which the LSC is organized is to be decided by Departments, Centers, Institutes (e.g., building), or other units under the advisement of the Provost, Dean, or Department Chair. Each LSC is chaired by a **Safety Coordinator** (SC) and it is recommended that this be an individual with relative seniority within the unit represented by the LSC.

The LSC will serve as a conduit between RMS and research personnel. The LSC must ensure that information is communicated both ways and that personnel have undergone required, documented training. As part of this, the LSC must develop a **Safety Program**, preferably

accessible online, to outline expectations, policies and general practices to research personnel relevant to the type of research and risk for the laboratories within the unit. The Safety Program would typically include policies, procedures, and training requirements for the risks associated with that laboratory.

Additionally, the Safety Program should determine circumstances requiring additional laboratory-specific hazard training. Importantly, the LSC will determine in collaboration with RMS, the **acceptable scope and depth** of the program needed to mitigate risk**.** RMS will work with the LSC to evaluate laboratories within the unit and identify those that must be validated under the Laboratory ISP. The SC serves as the main point of contact in these activities. Particularly important, the **SC contacts laboratories, provides key personnel with information related to the Laboratory ISP, and ensures that laboratories undergo the validation process.**

RMS serves as an overarching resource by providing information and guidance to LSCs and research personnel. This includes serving as a resource for training of personnel with respect to general hazards. Once a LSC has developed a Safety Program, RMS will approve it for content (i.e., regulatory compliance) and comprehensiveness; and RMS will review the Safety Program of individual laboratories during the Joint Assessment process described later in this document. Provisions for appealing decisions are described below in the appropriate section. RMS will coordinate and conduct annual joint safety assessments, and unannounced visits of laboratories in conjunction with Principal Laboratory Contacts who are identified for each laboratory. Once an EH&S training management system is put in place, **RMS will also serve as a coordination hub for documentation** of laboratory validation status and correction status of identified deficiencies. Further, RMS will alert personnel to the need to complete or update training and will maintain software tools to track training and compliance.

II. Definitions

Joint Assessment - Conducted initially for Safety Validation of laboratories and annually for continued Safety Validation, the Joint Assessment is the process by which a representative from RMS and the Principal Laboratory Contact conduct a safety assessment of the laboratory. The Joint Assessment is initiated by RMS and scheduled with the Principal Laboratory Contact. It should be noted that RMS may also conduct unannounced visits to laboratories, with or without the Principal Laboratory Contact, as it deems necessary. As part of the Joint Assessment, RMS and the Principal Laboratory Contact will review facilities, equipment, policies, training, and any other aspects related to safety, including the Laboratory Safety Protocol if one has been developed as directed by the unit Safety Program.

Laboratory - Any site where research or teaching involving risk to personnel is conducted falls under the definition of laboratory. Included in this definition are sites where bench research is conducted, field sites, and any other research or teaching activity which involves potential exposure to hazardous materials such as those defined in the University of Notre Dame Safety Policy (Policy 5.6), equipment, or other risks to safety. This definition includes any such research conducted either at sites owned or leased by the University and at sites not owned or leased by the University (although only laboratories and sites which are owned or leased by the

University must undergo Safety Validation as described later in this document). Core research resources are included in this definition. Not included in this definition is research conducted entirely via computer simulation; and that which is comprised entirely of data/information analysis.

Laboratory Safety Protocol - In cases where there are unique hazards, the LSC as part of the Safety Program might require a laboratory to develop a Laboratory Safety Protocol. The Laboratory Safety Protocol should clearly describe the hazard and the training, equipment, and processes that will be followed to mitigate risk to personnel.

Local Safety Committee (LSC) - Local Safety Committee (LSC) is appointed by the head (or his/her designee) of a unit to which the laboratory belongs, such as a College, Department, or Center/Institute. The LSC consists of members who are representative of research and teaching laboratories within the department, center, or institute. It is recommended that the LSC include T & R faculty, research faculty, special professional faculty, senior research technicians, post-doctoral associates, and graduate students. Further, a representative from RMS may be included as a member of the LSC. It is the job of the LSC to develop and implement policies and practices consistent with a safe work environment in research laboratories, working with Principal Laboratory Contacts in laboratories and RMS. In this regard, the LSC must develop a Safety Program for the unit as described later in this document.

Principal Investigator (PI)/Supervisor - The PI/Supervisor is the individual to whom all other personnel within a research or teaching laboratory (as defined above) report.

Principal Laboratory Contact - The individual within a laboratory who has been designated as the point of contact for RMS and personnel working within the laboratory. This definition is not meant to preclude direct interaction between RMS and any personnel; rather, it is meant to define a specific point through which information is expected to flow on an ongoing basis. The Principal Laboratory Contact is the individual who RMS contacts to schedule Joint Assessments and with whom RMS and the LSC work to fill gaps in risk mitigation. Though the PI/Supervisor or instructor may serve as the Principal Laboratory Contact, he or she may also designate other senior personnel such as technicians, post-doctoral associates, or graduate students to fill this role.

Risk Management and Safety (RMS) - The University of Notre Dame Risk Management and Safety Department.

Safety Coordinator (SC) - Appointed by the Department Head, or Center/Institute Director, the SC serves as Chair of the LSC. The SC is the main point of contact for the LSC.

Safety Program - Developed by each LSC to meet local needs, the Safety Program defines training required for individuals and serves as a ready source of information for mitigation of risks related to activities performed in laboratories within the unit. The Safety Program should include overarching University expectations for safety practices, and also include such information on a more local level with special import to risks within the local unit. Further, the Safety Program should include a mechanism which ***documents*** assessment and compliance with

safety down to the level of individual personnel particularly as it relates to training. RMS will work with the LSC to develop the Safety Program and will approve the Safety Program for each unit. The LSC should review and update the Safety Program on an annual basis, with updates submitted to RMS.

Safety Validation - Every laboratory must be evaluated by RMS to determine if significant safety risks exist. All laboratories determined by RMS to be housing significant safety risks must be Safety Validated. The process consists of conducting an initial and annual Joint Assessment, with RMS, of the laboratory safety status and remediating any deficiencies noted relevant to safety and risk mitigation, or providing a plan and schedule for correction of deficiencies which is determined by RMS to be adequate.

Specific roles of each component are further explained below.

III. Background and Overview

Safety is a priority for the University of Notre Dame as stated in the University of Notre Dame Health and Safety Policy (Policy 5.6). A safe working environment arises out of concern for, and the ethical obligation to, safety of colleagues and co-workers through risk mitigation. The Laboratory ISP is a means to validate that safe practices in the research and teaching environments are in place; this results from a process of risk assessment and mitigation. At its core, the Laboratory ISP **requires all personnel to accept responsibility** for ensuring the safety of themselves and others; and **all laboratories will be evaluated by RMS to determine if they are required to undergo Safety Validation.**

The overarching structure of the plan is to enhance the partnership between RMS and those working in teaching and research laboratories wherein safety practices can be assessed and optimized at the local level. Key to this is for units to develop a process which serves to link personnel and RMS and which serves as a local resource for investigators in implementing safe work practices. This goal aligns itself well with University goals of Research Advancement, Catholic Character, and Operational Excellence.

The Laboratory ISP creates a structure for managing safety and health at a local level, but with the benefit of RMS as a resource. Taking a structured approach to safety and health will yield an enhanced safety culture, reduced risk of injury, and improved regulatory compliance.

It must be stressed that the Laboratory ISP recognizes the need for flexibility with respect to how best to implement safety practices. In this regard, **the Laboratory ISP takes a non-prescriptive approach with this plan and expects each unit to collaborate with RMS and the LSC to institute a Safety Program that represents the "best fit" for safety practices based on circumstances, regulatory requirements, and widely accepted best practices.** In practice, it is anticipated that the LSC will issue the Safety Program for their unit.

IV. Who Is Required to Participate in the Laboratory ISP?

Participation in this program is required for all individuals participating in research or teaching conducted in a laboratory environment, including those conducted off-campus and at field sites. Specifically included are:

- Anyone conducting research as an employee at the University, whether in a laboratory or a field situation (This includes principal investigators, faculty, post-doctoral associates, staff, such as laboratory technicians and assistants, and students employed for the conduct of laboratory research or teaching activities)

- Unpaid students or personnel conducting research at the University, whether in a laboratory or a field situation

- Individuals participating in a teaching laboratory

- Visiting scientists or students participating in laboratory teaching or research

- Individuals entering a laboratory for any purpose (including ancillary functions such as facility maintenance)

- Non-University personnel or entities using University facilities for research or teaching activities (e.g., external core facility users)

- Individuals conducting research, in their capacity as either employee or student of the University, at a site neither owned nor leased by the University

The extent to which any individual must participate in the program and undergo training is determined by the LSC and RMS. Thus, the Safety Program developed by a LSC might require substantial training and documentation for those exposed to certain hazards, yet exposure to other hazards or low-level exposure may require less rigorous, or even no, training. It is up to the LSC, in consultation with RMS, to identify hazards within the unit's laboratories and to outline methods to mitigate associated risk.

V. Benefits of the Laboratory ISP

The Laboratory ISP creates a structure for managing safety and health within the department. Taking a structured approach to safety and health will yield numerous benefits to personnel, primary among these being an enhanced safety culture with reduced risk of injury. Additionally, as the Laboratory ISP is a programmatic initiative of the University intended to identify and mitigate known and foreseeable risks; University personnel responsible for laboratory safety acting within the scope of their employment in a reasonable manner and in accordance with the Plan will be afforded legal protection of the University in the event that claims arise out of operations covered by this program.

VI. Required Elements of the Laboratory Integrated Safety Plan

1. Units (i.e., Colleges, Departments, or Centers/Institutes) must establish a Local Safety Committee and assign a Safety Coordinator.

2. Each LSC must develop a Safety Program for the Unit. When unique hazards or unique circumstances warrant, **individual laboratories may also need to develop an individualized Laboratory Safety Protocol** to address specific risks.

3. Every laboratory must be part of a unit which maintains a LSC.

4. Every laboratory must be evaluated by RMS to determine if significant safety risks exist. All laboratories determined by RMS to be housing significant safety risks must be Safety Validated.

5. All research personnel must undergo documented training as specified by RMS, the Unit's Safety Program, and the laboratory in which work is being conducted. Though training might be provided by RMS or other sources, including other laboratory personnel, all training must be documented centrally at RMS, once a training record management system is in place, or locally within the laboratory. Documentation should be available when requested by the LSC or RMS.

VII. Areas of Responsibility

A. University Leadership

The University leadership endorses the University of Notre Dame's Health and Safety Policy requiring that the University leadership maintain a safe work environment within their jurisdiction, and by monitoring and exercising control over their assigned areas. The University leadership has further responsibility for ensuring sufficient and proper resources are made available as needed to meet the needs of laboratory and research safety programs.

B. Risk Management and Safety (RMS)

RMS responsibilities include:

1. ***Train and assist the LSCs*** so that they fully understand their tasks and are equipped to properly engage their responsibility.

2. ***Provide guidance*** and informational resources to guide LSCs and laboratories.

3. ***Develop mechanism for interface*** with LSCs so that relevant safety and regulatory information can be communicated to end users in a timely manner.

4. ***Provide templates*** to LSCs for development of the Safety Program for the area over which the LSC has domain.

5. ***Provide oversight*** to ensure conformance of safety processes with requirements.

6. ***Evaluate*** laboratories to determine if there exists significant risk which requires the laboratory to undergo the Safety Validation process.

7. ***Conduct joint Safety Validation*** assessments of laboratories.

8. ***Track laboratory validation status*** to ensure that all relevant laboratories are enrolled in the validation process; that all deficiencies noted in the Joint Assessment or otherwise reported are corrected; and alert laboratories and SCs of approaching annual Joint Assessments.

9. ***Provide centralized documentation of safety training of personnel***. Although the LSC may determine that some training records are most appropriately maintained by individual laboratories, RMS will maintain a resource that allows for a centralized database of personnel training once a training record data management system is in place.

10. ***Stop a process or procedure*** that poses an imminent danger to life or property.

11. ***Track reports of injury, accidents, work-related illness, or exposures*** to hazardous agents and provide LSCs with information in a manner and at a frequency that allows timely investigation and intervention for risk mitigation. A summary of such incidents should be supplied to the relevant LSC at least annually for their review as a metric of efficacy of the unit's Safety Program.

C. Deans, Provost, Department Heads, Center/Institute Directors, or Designee

The Dean, Provost, Department Chair, or Center/Institute Director or his/her designee should facilitate a safe workplace and implement the safety and health programs by undertaking the following responsibilities:

1. ***Embrace a culture of safety*** and establish and demonstrate an expectation that all personnel will follow policies and procedures to ensure safety. This includes communicating to all faculty, employees and students that health and safety of persons in the workplace are of the highest priority within the unit and at the University of Notre Dame; ensuring that expectations established by this program applicable to their areas of jurisdiction are carried out; supporting measures such as training and use of protective devices; and providing resources to control and prevent hazards. A unit Mission Statement is a good initial step in this regard, and guidelines are attached to this document as Appendix 1.

2. ***Establish and maintain a Local Safety Committee***. This includes appointing both a SC and a LSC. The size and structure of the LSC shall be dictated by the types of activities and the potential hazards inherent to those activities. It is recommended that the

membership be representative and include T & R faculty, research faculty, special professional faculty, senior research technicians, post-doctoral associates, and graduate students. Further, a representative of RMS might be included as a member of the LSC. It is recommended that the SC be an individual with relative seniority within the unit. In some cases, creation of several LSCs may have value within a unit.

3. ***Enable enforcement of rules and regulations***, and take prompt, effective corrective action when necessary.

4. ***Provide assistance*** to RMS and the LSC when situations arise that threaten the safety of investigators and other personnel in the department.

5. ***Identify resources*** needed to address risk mitigation efforts that exceed the ability of the laboratory. This is likely done in conjunction with the LSC and the Principal Laboratory Contact. The process for requesting resources is described in Section VIII, The Joint Assessment Process.

D. Safety Coordinator (SC)

Appointed by the Department Head or Center/Institute Director to lead the LSC, the specific responsibilities of the SC include:

1. ***Coordinate meetings*** and activities of the LSC.

2. ***Maintain minutes*** of LSC meetings as well as other documents/information.

3. ***Serve as the point of contact*** within the unit for safety-related concerns and questions, and for the LSC.

4. ***Act as an intermediary*** between RMS, the laboratory personnel, and the Dean, Department Chair, Center/Institute Director, or his/her designee to facilitate solutions to noncompliance issues. This includes helping identify resources needed to address risk mitigation situations that require resources beyond the ability of the laboratory. The process for requesting resources is described in Section VIII, The Joint Assessment Process.

5. ***Ensure reporting*** of injuries, accidents, and exposures to RMS. Assist in investigating precipitating circumstances, and work with RMS and laboratory to mitigate future risk.

6. ***Report***, at least annually, to the Provost, Dean, Department Chair, Center/Institute Director, or his/her designee the current status of laboratory safety validations; injury, accident, and exposure incidents; and existing gaps in laboratory safety resources and infrastructure.

E. Local Safety Committee (LSC)

The LSC comprises members representing all aspects of risk and hazard within the unit. The duties of the LSC are described in Appendix 2 and include:

1. ***Develop and implement***, under the guidance of RMS, a comprehensive and practical **Safety Program** for the unit that identifies participants, establishes training expectations for the participants, and serves as a ready source of information regarding risk mitigation relevant to activities performed in laboratories within the unit. **If unique hazards or special circumstances warrant, an individual laboratory may be directed to develop a Laboratory Safety Protocol to address measures taken to mitigate specific risks.** Guidelines for the Laboratory Safety Protocol are provided in Appendix 2.

2. ***Annually review*** the Safety Program for currency and comprehensiveness.

3. ***Work with RMS and the SC*** to formulate plans for ensuring evaluation of all laboratories for risk and safety validation for those laboratories determined by RMS to be housing significant safety risk. **This includes providing to RMS the location of all laboratories, name of the PI/Supervisor and Principal Laboratory Contact in charge of all laboratories**.

4. ***Serve as a conduit for safety information*** from RMS to personnel within the unit by assisting the SC as requested in efforts to educate and update personnel on research laboratory safety issues. Also, the LSC serves as a conduit for personnel to report safety concerns about laboratories and helps to resolve concerns.

5. ***Review*** reports from RMS of employee accidents or work-related illness. This includes assisting in the investigation of all serious accidents, and all other accidents when requested by RMS. This information should be shared with the next higher level within the administrative lineage at least annually as a metric of the unit's Safety Program.

6. ***Review*** the results of Joint Assessments conducted by RMS and Principal Laboratory Contacts of laboratories within the unit; and work with Principal Laboratory Contacts to develop plans and schedule for correction of any deficiencies noted; if needed, work with the Dean, Provost, Department Chair, Center/Institute Director if he/she has determined that the remediation requires resources beyond those available to the laboratory. Further, when appeals are made in response to the results of Joint Assessments or unannounced visits by RMS, the LSC will evaluate such appeals and, if merited, meet with RMS for resolution as described later in this document. The appeals process is described in Section VIII, The Joint Assessment Process.

7. ***Communicate*** with the Dean, Provost, Department Chair, Center/Institute Director, or his/her designee with respect to validation status of laboratories within the unit; to request resources needed to address safety and risk mitigation concerns; and to communicate data regarding laboratory workplace injuries, illnesses, and exposures.

F. Principal Investigators (PI) and Supervisors

The PI or Laboratory Supervisor is responsible for promoting practices to mitigate risk associated with research under his or her purview. This individual must be aware of the physical and health hazards likely to be present in the laboratory.

Specific responsibilities are:

1. ***Inform*** all employees and students that safety and health are priorities; and inform them about safety and health policies, rules, regulations and procedures, as well as their specific responsibilities, as determined by the LSC.

2. ***Work with the LSC and RMS*** as appropriate to maintain safety practices for the laboratory. This includes ensuring that personnel in the laboratory participate in the local **Safety Program** as required.

3. ***Develop a Laboratory Safety Protocol*** if required by the Safety Program of the Unit. The PI or Supervisor may task another individual within the laboratory to construct the Laboratory Safety Protocol, though the PI or Supervisor is responsible for ensuring the task is satisfactorily completed.

4. ***Identify*** hazards within the laboratory and implement practices which mitigate risk.

5. Ensure that personnel in laboratories complete training in the proper operation of equipment or use of materials involved in any procedure that may be potentially hazardous; and that they participate in the RMS centralized laboratory safety training documentation process once established. Alternatively, training provided locally may be documented separately; however, records for such training must be made available to RMS and the LSC when requested.

6. ***Set expectations and require that safety equipment***, devices, personal protective equipment, and apparel are provided and maintained, and are properly used by individuals present in the laboratory, including personnel from other laboratories. Likewise, the expectation must be set that individuals working under the PI or supervisor complete training and operate under the relevant expectations and requirements when present or using equipment in other laboratories. In the case of laboratories occupied by multiple PIs, each PI or supervisor has these responsibilities for personnel working under his/her oversight.

7. ***Take prompt corrective action*** when unsafe conditions, practices or equipment are reported, observed, or when identified during Joint Assessments or unannounced assessments.

8. ***Encourage prompt reporting*** of health and safety concerns to at least one of the following: RMS; the SC; the LSC; the Principal Laboratory Contact; or the PI/Supervisor.

9. ***Promptly report*** all work-related injuries, illnesses, accidents, and exposures to hazardous agents to RMS and the SC; and collaborate with RMS to investigate all such incidents and implement means to mitigate risk if needed.

10. ***Assign*** a Principal Laboratory Contact, such as the PI, or other senior member of the laboratory, to serve as the primary point-of-contact for safety issues and having responsibilities as described in VII.G of this Policy.

11. ***Provide financial support*** for health and safety improvements, or request assistance from the next higher level of supervision regarding these requests.

G. Principal Laboratory Contact

The Principal Laboratory Contact is the individual designated by the PI or Supervisor to act as the primary interface with the LSC and RMS. In this regard, the Principal Laboratory Contact has several specific responsibilities:

1. ***Interface*** with RMS and the LSC regarding safety expectations.

2. *Communicate* to laboratory personnel information from RMS and LSC relevant to laboratory safety and ***promote*** laboratory safety practices and policies.

3. *Schedule and collaborate* with RMS to conduct Joint Assessments.

4. *Work with RMS to train and document* laboratory personnel with respect to proper safety procedures in the laboratory, including provision of laboratory-specific training for unique, specific hazards within the laboratory. While some training may be best provided by RMS or other sources, including other laboratory personnel, all training must be documented centrally at RMS once a record management system is put in place or locally within the laboratory. Documentation should be available when requested by the LSC or RMS.

5. *Ensure prompt reporting* by personnel of all work-related injuries, illnesses, accidents, and exposures to hazardous agents to RMS, the PI/Supervisor, and the SC. In addition, collaborate with RMS to investigate all such incidents and implement means to mitigate risk if needed.

H. The Individual

Each individual working in a laboratory or other work-site where safety risk exists is expected to know and comply with the University's safety policies and rules; and to follow both oral and written instructions from the Principal Laboratory Contact, the PI, the LSC, and RMS. The individual must report to the PI, the Principal Laboratory Contact, the LSC, or RMS any unsafe conditions and any accident, including unsafe exposure to chemicals, radiation, or biological agents. In the case of an accident, work-related illness or exposure to hazardous agents, the

individual should seek medical treatment. In the case of unsafe conditions, if the individual receives no response or an unsatisfactory response from the PI or the Principal Laboratory Contact, he or she must contact the SC or RMS.

Specific responsibilities of individuals are:

1. ***Comply*** with applicable environmental health and safety policies, standards, rules, regulations and procedures as established by the laboratory and the unit's Safety Program. These include safety-related signs, posters, warnings, and written/oral directions when performing tasks; also included is wearing personal protective equipment as instructed.

2. To ***not perform any function or operation that is considered hazardous*** without proper instructions and authorization.

3. ***Use only equipment and materials approved*** or provided by the PI/Supervisor, and for which instruction has been provided.

4. ***Become knowledgeable*** about potential hazards associated with the work area; knowing where information on these hazards is maintained and how to use this information when needed.

5. ***Wear or use*** and properly maintain prescribed protective equipment.

6. ***Report*** all unsafe conditions, practices, or equipment to the PI, the Principal Laboratory Contact, the LSC, or RMS whenever deficiencies are observed. In most cases, it is preferable to report such conditions directly to the PI.

7. Inform the Principal Laboratory Contact, PI/Supervisor, or RMS promptly of all work-related injuries, accidents, and exposures to hazardous agents; and obtain prompt medical attention when needed.

VIII. The Joint Assessment Process

The Joint Assessment process is conducted initially, then annually, by RMS and the Principal Laboratory Contact. The LSC is responsible for providing to RMS the locations of all laboratories within the unit for which the LSC is responsible and the names of PIs/Supervisors who are responsible for those laboratories. RMS will then evaluate each laboratory to determine if it needs to be included in the Joint Assessment process and undergo a Safety Validation. Similarly, LSCs should notify RMS when new laboratory operations are opened and when there is a material change in an existing laboratory operation that substantially changes the risk to personnel.

If it is determined, after evaluation of a laboratory that it qualifies for Safety Validation, the Joint Assessment is initiated by RMS requesting the name of a Principal Laboratory Contact from the

PI/Supervisor. RMS then contacts individual Principal Laboratory Contacts to schedule a Joint Assessment visit. The Joint Assessment is a means to review all key areas of safety within the laboratory. Together, the RMS representative and the Principal Laboratory Contact will review relevant aspects of safety to ensure that proper risk mitigation is in place. RMS will subsequently write a Joint Assessment report which includes the date and names of participants in the Joint Assessment, with copies sent to the PI/Supervisor, the Principal Laboratory Contact, and the LSC. The Joint Assessment is meant to be a collaborative process in which safety gaps are identified and solved collaboratively.

In instances in which appropriate risk mitigation is lacking or could be improved, RMS determines, in collaboration with the Principal Laboratory Contact, specific actions and timelines that would be acceptable to address the deficiency. The Principal Laboratory Contact then must provide to RMS and the SC/LSC, within a period determined by RMS and the Principal Laboratory Contact at the time of the Joint Assessment, a written plan and schedule for correction of all deficiencies noted during the Joint Assessment, including those already addressed. RMS will review the response for adequacy. Likewise, the LSC should regularly review Joint Assessment reports and responses to ensure that an appropriate level of safety is being maintained in laboratories under its purview. Though part of a collaborative process, RMS will make final determinations on acceptability of plans and schedules for correction of deficiencies, and the deadline for submitting such plans and schedules.

When disagreement arises regarding plans and schedules for correction of deficiencies, the following appeal process should be utilized: The Principal Laboratory Contact should contact the SC, in writing, detailing the reason for the appeal. The LSC will then consider the appeal, and if approved, will meet with RMS to negotiate resolution of the disagreement. If not approved, the schedule and plan decided by RMS must be followed, though the Principal Laboratory Contact may then appeal the decision of the LSC to the Vice President for Research or his/her designee. Likewise, if the LSC and RMS are unable to reach a mutually agreeable resolution, the LSC may then choose to appeal to the Vice President for Research or his/her designee. Decisions made by the Vice President for Research or his/her designee shall be final and binding as a condition for Safety Validation of the laboratory.

When correction of deficiencies is believed to require resources exceeding those of the laboratory, the Principal Laboratory Contact should contact the LSC via the SC. A course of action to address the deficiency will be determined in conjunction with the LSC. Possible measures might include identifying alternative approaches to mitigation for consideration by RMS; or requesting needed resources from a higher level within the University. As with the Joint Assessment, this aspect of addressing safety gaps should be collaborative, with RMS endorsing requests for resources **when appropriate** and considering suggested alternative approaches to risk mitigation.

RMS may also conduct unannounced safety assessment visits as described elsewhere in this document, and the documentation and response expectations are the same as for scheduled Joint Assessments.

In cases where laboratories (i) refuse to undergo Joint Assessment, (ii) significant safety risks are identified, (iii) failure to formulate a plan and schedule for correction of deficiencies acceptable to RMS, or (iv) a mitigation plan is not adequately adhered to, Safety Validation may be revoked and/or sanctions may be applied (see Section IX below).

IX. Revocation of Safety Validation

The Department of Risk Management & Safety (RMS) may conduct periodic safety assessments, announced or unannounced, to identify new or unresolved compliance issues and potential hazards within a laboratory. In the case of unannounced assessment visits, the laboratory must comply to allow entry and assessment by RMS, though it is expected that RMS and the laboratory will mutually identify a means for assessment if such visits would place research or personnel at risk. Unannounced visits will be in addition to the scheduled annual assessment of individual laboratories.

Failure to execute, maintain or make adequate progress regarding standards for Safety Validation may result in revocation of Safety Validation for the laboratory. This includes the identification of any grave safety issue that poses an immediate threat to life or health. Whereas Safety Validation is required for all relevant laboratories as determined by RMS, revocation may lead to specific sanctions (see below).

In situations of critical risk or ongoing risk that is not properly mitigated, the SC will work with the Principal Laboratory Contact to address the situation. If mitigation does not result, the next higher level within the administrative lineage of the SC (i.e., Dean, Provost, Department Chair, Center/Institute Director, or his/her designee) will be advised by the SC and will work with the Principal Laboratory Contact to address the situation. If mitigation or a plan and schedule for mitigation do not subsequently result, RMS may revoke Safety Validation and sanctions may be applied to the laboratory as described below.

X. Application of Sanctions

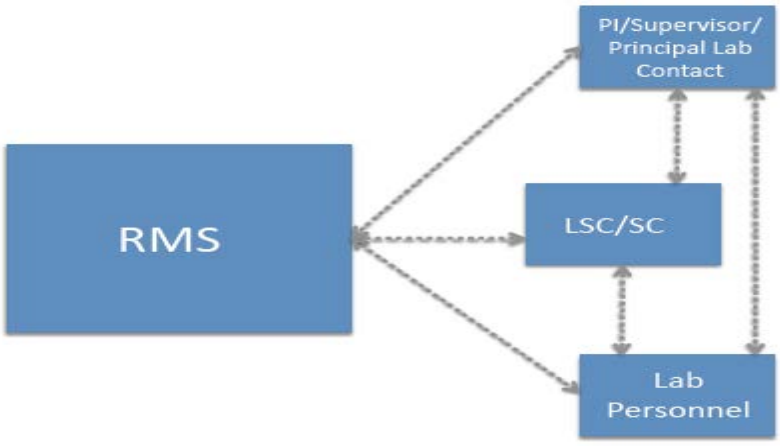
As safe work practices are a cornerstone for a successful research and teaching enterprise, **all laboratories determined by RMS to be housing significant safety risks must be Safety Validated**. Laboratories that are not Safety Validated or have personnel engaging in unsafe work practices may have sanctions applied. Examples of sanctions which may be applied are:

- Re-training of personnel
- Withholding of University and/or external funds
- Notification to funding agencies of compliance issues
- Barrier to submission of research or teaching proposals

- Withholding/revocation of regulatory approvals (IACUC, IBC, REM, IRB, RCC, etc.)
- Laboratory access restriction of specific personnel
- Closure of laboratory

The decision to apply specific sanctions will be at the discretion of the administrative level above the LSC (i.e., Dean, Provost, Department Chair, Center/Institute Director, or designee) under advisement of the LSC and RMS. However, in the event RMS determines there is an immediate threat to life or health, RMS has the authority to close or restrict access to a laboratory. If the recommendation for sanctions by the LSC and RMS to the Dean, Provost, Department Chair, Center/Institute Director or designee is not applied, the LSC and/or RMS may appeal to the Vice President for Research or his/her designee for application of binding sanctions. On the other hand, if sanctions are applied by the Dean, Provost, Department Chair, or Center/Institute Director or his/her designee, the laboratory or individual to which/whom sanctions are applied may appeal to the Vice President for Research or his/her designee; however, any decision of the Vice President for Research or his/her designee shall be final and all resulting sanctions binding. In all cases, the specific sanctions applied should be commensurate with the circumstances.

Integrated Laboratory Safety Plan



The Laboratory ISP is meant to be a collaborative effort, with ready communication between RMS, PIs, Principal Laboratory Contacts, LSCs, and laboratory personnel and students.

XI. Appendices

Appendix 1 - Guidelines for Developing a Mission Statement

The establishment of a "Safety Statement" is a good first step in implementing the Laboratory Integrated Safety Plan within a College, Department, Center, or Institute. The general purpose of such a statement is to express leadership's commitment to workplace safety and health. It must also clarify safety and health responsibilities throughout the work group. It should be viewed as a concise (usually one page) document that summarizes the group's support of the University of Notre Dame Health and Safety Policy, which can be accessed at: http://riskmanagement.nd.edu

This information is intended to help you develop your statement. It has been split into the following four headings: introduction, purpose/goal, safety responsibilities, and closing. Each of these sections includes excerpts from other statements. These are examples only, but they may give ideas for developing a statement that expresses your style, attitudes, and values.

Introduction

The written statement generally starts with a clear, simple expression of your concern for employee safety and health. Examples of statement introductions are as follows:

- It is the policy of this department to provide a safe and healthy workplace for all employees.

- This department considers no phase of its operation or administration more important than safety and health. We will provide and maintain safe and healthy work conditions, and we will insist on safe work methods and practices at all times.

- This department has always believed that our employees are our most important asset. We will always place the highest priority on safe operations and the safety and health of employees.

Purpose or Goal

Effective safety and health efforts will have a stated purpose. This is included so that all employees are clear on why resources are devoted to safety. You may want to consider incorporating material similar to the following:

- Our objective is to have a safety and health system which will minimize losses with an ultimate goal of zero work-related injuries and illnesses.

- We have established our safety and health system to eliminate work-related injuries and illnesses. We expect it to improve operations and reduce personal and financial losses.

Safety Responsibilities

The statement needs to describe in general terms what the safety responsibilities are at each level of the unit. It should not include a detailed list of all responsibilities, but rather give each individual a basic understanding of what their role is within the overall safety effort. This portion

of the statement is often broken down in terms of management, supervisory, and employee responsibilities:

- Management is responsible for leadership of the overall safety effort and providing all resources which are necessary for an effective program of accident prevention.

- Supervisors are responsible for maintaining safe work conditions within their areas and ensuring that all operations are carried out with the utmost regard for safety.

- Each employee is responsible for consistently following all established safety procedures and promptly reporting potential hazards.

Closing

The closing is a reaffirmation of the unit's commitment to a safe and healthy workplace. It may also offer an appeal for the cooperation of all employees in supporting safety efforts. Examples are as follows:

- All employees are strongly urged to make safety and health an integral part of their daily activities.

- By accepting mutual responsibility to operate safely, we will contribute to the well-being of one another and consequently the entire University.

- The safety and health efforts within this department are intended to protect our most valuable asset: our employees. Maintaining a safe work environment is a top priority of leadership and must be a personal goal of every employee.

Once the Laboratory ISP mission statement is finalized, it should be publicized within the unit.

Appendix 2 - Local Safety Committee Information

The following is a list of **suggested responsibilities** that can be adopted by a LSC:

- Provide information to RMS in a timely manner that identifies location of laboratories and the names of PIs/Supervisors and Principal Laboratory Contacts responsible for such laboratories
- Define committee responsibilities
- Establish effective communication plans for safety issues
- Review safety concerns and suggestions made within the unit
- Review results of Joint Assessments made for laboratories within the unit
- Develop mechanisms to implement new safety policies and procedures within the unit
- Ensure safety training needs within the unit are met
- Review injury reports and trends within the unit
- Exchange relevant information with RMS
- Identify the most critical safety issues for focus and funding
- Help define feasible solutions to safety issues in cooperation with RMS
- Maintain records of all committee meetings

Meeting Agenda Guidelines

The following is a list of recommended agenda items for department safety committees:

- Review minutes of previous meeting
- Review communication of safety issues, policies, Laboratory Safety Protocols, or procedures within the unit
- Discuss accident reports and trends, causes of accidents, and preventive/corrective actions
- Review unsafe conditions reported within the unit and how addressed
- Discuss emergency response issues pertinent to the unit

- Discuss Joint Assessment and unannounced visit results and coordinate follow-up

- Reserve time to cover a specific "safety topic" at each meeting (guest speaker, training)

Guidelines for LSC Structure

The following are basic guidelines for determining the membership of Local Safety Committees:

- Membership should consist of individuals representing various areas within the unit. This might include faculty, post-doctoral associates, graduate students, and staff researchers. A representative of RMS might also be included.

- The committee should consider forming subcommittees when appropriate for larger tasks or initiatives. If appropriate, the LSC should consider adding ad hoc members to provide expertise in specific areas when needed.

Guidelines for Frequency of Meetings

The following are basic guidelines for determining how often the LSC should meet:

- Each LSC should meet on at least a semi-annual basis

- More frequent meetings may be appropriate depending on the nature of operations, number of employees, etc.

- Other functions can occur between safety committee meetings as needed

Guidelines for the Safety Program

The LSC is charged with developing and maintaining a Safety Program that outlines expectations, provides safety information, and requires a mechanism for documentation that ensures individuals exposed to hazards are appropriately informed and qualified. Where special hazards warrant, the Safety Program might specify individual laboratories create their own **Laboratory Safety Protocol** that addresses specific risks within those laboratories. The Laboratory Safety Protocol would typically include policies, procedures, and training requirements (and records if the laboratory decides to keep these locally in addition to those maintained in the centralized RMS training record) for the risks associated with that laboratory. Laboratory Safety Protocols will be reviewed by RMS as part of the Joint Assessment process for those laboratories required to maintain such a plan.

In this regard, there are several important points with respect to the Safety Program:

1. Expectations from the head of the unit with regard to compliance of personnel with the Safety Program should be stated.

2. The Safety Program should define hazards within the unit and address training to mitigate risk associated with those hazards. Training might be provided by PIs or other qualified individuals such as RMS safety professionals. In all cases, training should be documented for those hazards determined by the LSC and RMS to pose substantial risk; and training of personnel should be documented through the RMS central training record system once it is put in place and/or locally within the laboratory in a way which will allow ready retrieval of training records. The Safety Program should also seek to identify activities that, while permissible in the laboratories, are of a sufficiently hazardous nature that they should not be performed alone.

3. The Safety Program should be in a format that is readily available to all individuals within the unit. Preferably, the Safety Program would be available online, as a link on the webpage of the Department, Center, or Institute for which the LSC is responsible. The Safety Program may also be administered via training sessions or printed material, or by combinations of these and online presentation. RMS can assist the LSC in identifying an appropriate format or template for development of the Safety Program. As the Safety Program must be approved by RMS, the LSC is strongly encouraged to consult with RMS in development of the Safety Program.

4. The LSC may determine that a **Laboratory Safety Protocol** which addresses measures taken to mitigate risk associated with specific research and teaching activities is needed for some laboratories which contain unique hazards. This would typically be needed when the unit Safety Program created by the LSC does not fully capture unique risks associated with a specific laboratory or activity. The Laboratory Safety Protocol should be written or online and describe risks, expectations for personnel regarding safety, training, personal protective equipment, and policies or standard operating procedures to be followed for the unique risks not captured in the LSC's Safety Program. The LSC and RMS should review and approve a Laboratory Safety Protocol before it is adopted. The Laboratory Safety Protocol will again be reviewed by RMS as part of the Joint Assessment.

5. The Safety Program should link to the RMS webpage for relevant guidance and regulatory documents.

6. Information regarding actions to be taken in the event of an injury, accident, work-related illness, or exposure to hazardous agents should be included.

7. If relevant to the unit, information related to risk mitigation for those traveling to conduct off-campus research or teaching at units or other locations which are, or are not, owned or leased by the University should be addressed in the Safety Program as described in Appendix 3. This should include informing PIs/Supervisors of the need to consult with the LSC to determine the need for developing a safety plan related to any off-campus research or teaching.

Once the Safety Program has been drafted, it must be approved by RMS. The LSC should review the Safety Program at least annually to ensure comprehensiveness and currency.

Appendix 3 - Laboratory Safety in Off-Campus Laboratories and Field Sites

Off-campus laboratory or field research and teaching (referred to from now on as off-campus activities for brevity) does not absolve participants or the LSC of the relevant unit from responsibilities for safety. Working safely in off-campus activities can present special challenges. For example, laboratories or field sites will generally not be able to participate in the Joint Safety Assessment process with RMS. In some settings, as for example, at labs in developed countries, the safety procedures and facilities may match or exceed those present on campus. In other cases, for example in developing countries or at field sites, facilities may not be comparable to those on campus, or may even expose participants to unusual hazards (such as those sometimes encountered in field settings). The goal of the Integrated Safety Plan is not to prevent research in such settings. Instead, the ISP should assist the PI and other participants with anticipating hazards and preparing to mitigate risk.

Because each off-campus situation will be unique, the Joint Assessment process used by RMS to assess safety on campus will probably not be very useful for off-campus laboratories that are not owned by Notre Dame, and the Joint Assessment process will almost certainly not be relevant to field settings. For this reason, **each LSC must determine, in consultation with RMS, which off-campus circumstances require defined safety protocols as part of either the unit's Safety Program or an individual Laboratory Safety Protocol.** The Laboratory Safety Protocol must address all elements of the PI's responsibilities as described in Section VII.G of the ISP that are appropriate for the specific off-campus setting.

Field research or teaching often includes specific hazards or challenges beyond those normally encountered in a lab setting. In addition to items commonly addressed in a Laboratory Safety Protocol (training, use of personal protective equipment, safe use of equipment, etc.), additional elements should include the following:

1. Identification of known significant safety problems or risks, and appropriate responses.

2. A description of the work plan and how it will be executed safely, consistent with the experience and training of the participants and the nature of the field site.

3. Requirement that each participant be advised to consider any existing medical condition (e.g., asthma, epilepsy, allergies, diabetes, etc.) so that the appropriate precautions may be taken. Each participant must be advised to maintain appropriate health insurance and evacuation insurance when prudent.

4. Personnel should be advised to reasonably undertake risk mitigation measures similar to those practiced on-campus; however, when such measures are clearly exceeded by the required measures and practices of the off-campus site, the latter should be followed.

5. All participants should be instructed what to do in the event of an accident or emergency. All personnel should know how to obtain help in an emergency; in some cases, it may be prudent to carry a first-aid kit.

6. The personal equipment and clothing of all participants should be suitable for all weather conditions, terrain, etc., likely to be met during the project.

7. Personnel must never work alone without the prior permission of site management staff.

8. Personnel should be advised to reasonably minimize the risk of accident during the transport of personnel and equipment to the research site and/or during the field work, irrespective of the ownership of the vehicles being used. Further, they should check with RMS if there are transportation requirements for any chemical or hazardous material being transported.

9. Field researchers must follow all applicable laws and regulations of the host country that apply to the field site. In addition, field researchers should be advised that the University has specific protocols and regulations regarding research undertaken outside of the United States. Faculty engaged in foreign research, especially when engaging Notre Dame students in their projects or when employing local workers, should consult the Notre Dame International website (http://international.nd.edu/) during the early stages of their planning to familiarize themselves with these policies and to access appropriate information and resources. Also, researchers should check with the Office of Research regarding export controls if taking or shipping equipment out of the country.