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Updated Biological Risk Management Program at CDC

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ABSTRACT

The principles of risk assessment, as the foundation of any safety discipline, should be put in practice in the daily performance of duties in the laboratory. **Methods:** To implement the updates to the risk management program CDC began by establishing a 6-hour course that included lecture, interactive review, and case studies/exercises. The course includes basic concepts such as hazard, risk, inherent risk, residual risk, risk mitigation, risk matrix, severity and probability, hierarchy of controls, and risk assessment as a continuous process. Simultaneous with the training program a new risk assessment tool was developed following the steps outlined in class, including hazard identification, risk evaluation, and risk mitigation. Then a risk assessment policy was enacted which required a risk assessment for all new or modified laboratory work and for the commissioning of new laboratories. Our risk management cycle also included an annual review requirement as well as record keeping and data analysis. **Results:** data and outcomes of the training program and the risk assessment review process will be discussed. **Conclusion:** The implementation of a risk management program is described. Similar steps can be taken at other institutions to enhance their safety posture. **Outcomes:** Increased awareness of risk assessment agency wide, increase in the number of risk assessments submitted for review, and a new systematic approach to risk management.

INTRODUCTION

Risk assessment (RA) is recognized in the biosafety field, and indeed all safety practice, as a critical element of laboratory work. The BMBL (5th edition) dedicates a whole section to risk assessment and provides a definition of it within its first few pages. The WHO Laboratory Biosafety Manual (3rd edition) indicates that risk assessment is the basis for the selection of the appropriate biosafety level. It is important that every institution take proactive steps to identify, evaluate, mitigate, and manage risks. To that end the CDC revised and updated its risk management program in 2015. In revising this program we view risk assessment as a continual process adaptable and responsive to new situations, additional scientific information, or newly collected data. Risk assessment is one of the most proactive tools available to institutions to address problems before they arise. Other tools are reactive, such as incident investigations, near misses, and answering queries. Risk assessment, combined with good data analysis, safety inspections, and training can have a significant Impact on the safety of laboratory staff.

METHODS

The following parts of the program were implemented or updated:

- Risk assessment course (new: 2015)
- Risk assessment form (revised biological risks:2015 new chemical risks: 2018)
- Risk assessment Policy (new: Nov 2016)
- Guidance document and FAQ (new: 2017)
- Communication (roll out: 2017)

The 6-hour biological RA course consists of lecture, review section, biological RA form step by step instructions, scenario-based exercise, and final exam. The course also included the concepts of inherent and residual risks, Risk tolerance, risk matrix (Table 1), risk mitigation and the hierarchy of controls (Fig. 1).

	SEVERITY				
Probability	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Low	Moderate	High	High	High
Probable	Low	Moderate	High	High	High
Occasional	Low	Moderate	Moderate	High	High
Remote	Low	Low	Moderate	Moderate	High
Improbable	Low	Low	Low	Moderate	Moderate

Table 1. Risk Matrix currently in use at the CDC. The matrix considers the two main variables for risk: severity and probability

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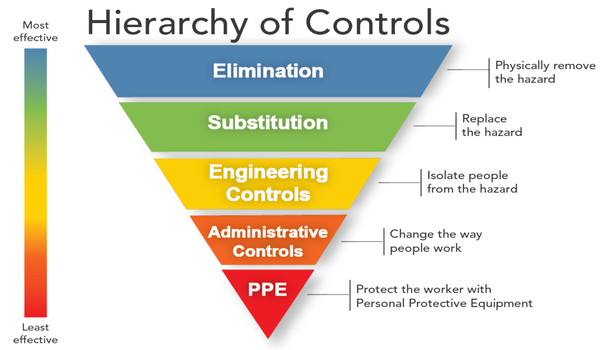

Figure 1. Hierarchy of controls indicating the most effective controls towards the top of this inverted pyramid as well as the ones requiring the most supervision towards the bottom. From: https://www.cdc.gov/niosh/topics/hierarchy/default.html

The RA policy, officially published in November of 2016, requires a risk assessment be performed on all new and modified procedures and newly commissioned laboratories.
The guidance document expands on and explains the policy requirements, to include centralized review of all RAs for select agents and risk group 3 and 4 pathogens.
Once all the documents were finalized and approved, the communication plan included an advertisement campaign involving newsletter announcement, publication on our intranet site, engagement sessions with laboratory leadership, and email communication.

RESULTS

- Over 460 students successfully completed the RA course from 2015 to 2018 and provided feedback by anonymous survey (Fig. 2). Students included laboratory supervisors, select agent principal investigators, quality managers, safety managers, laboratory researchers, and higher leadership.
- Current passing rate for the course is 95%.
- Minimum grade required to pass the RA course is 80%.
- Most CDC laboratories have completed at least one RA form.
- 133 RA reviewed centrally (majority reviewed at program level).
- Of the centrally reviewed RAs, investigators considered 65% to have moderate inherent risk (Fig. 3) whereas 91% estimated the residual risk to be low.
- As expected, the majority of RAs submitted for review covered laboratory work with RG2 organisms in BSL2 laboratories (Fig. 4)

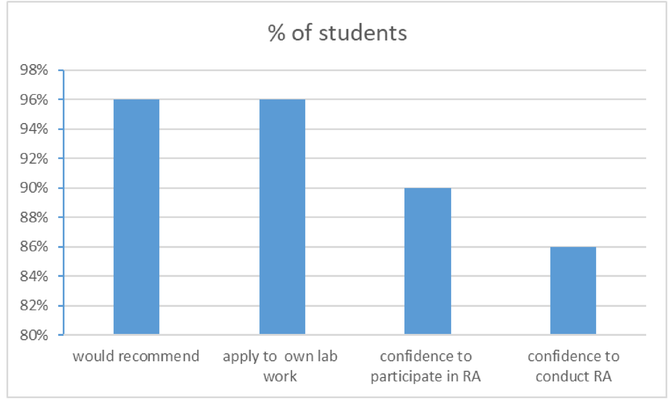

Figure 2. Feedback from risk assessment course students

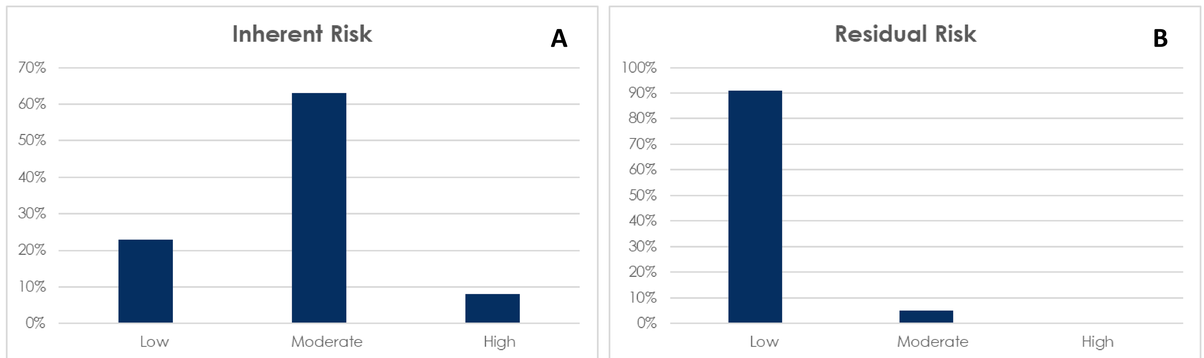

Figure 3. Inherent risk (A) and Residual risk (B) as estimated by laboratory staff in reviewed risk assessments

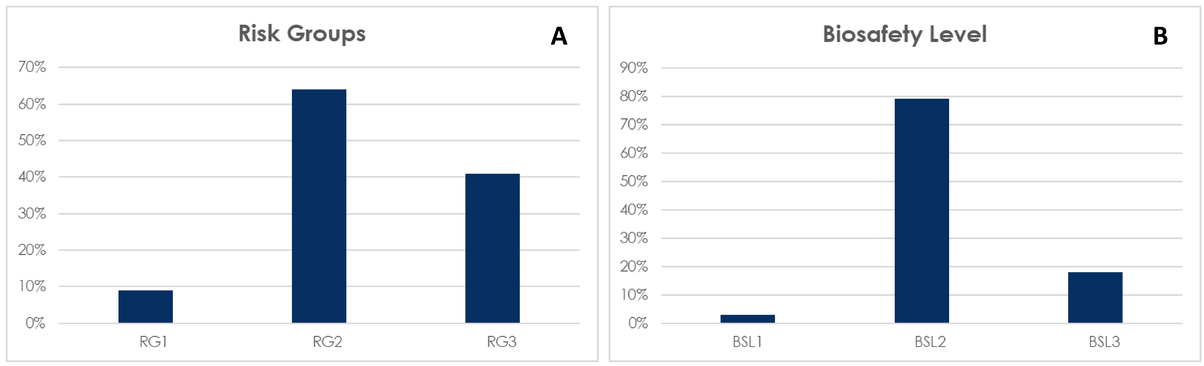

Figure 4. Breakdown of risk groups (A) and biosafety levels (B) indicated in reviewed risk assessments. As expected most of the work reviewed falls in the RG2 and BSL2 category

DISCUSSION

Prior to 2015 several elements of a risk management program existed at the agency. There was a short risk assessment form which was only used by a few programs within the agency. There were risk assessment classes offered to some audiences, such as the animal husbandry staff, but not to all laboratory staff. There was, however, no central policy or consistent application of risk assessment principles across CDC. What has taken place is a reorganization and implementation of risk management as an agency wide program with consistent tools and procedures, as well as clear expectations outlined in official policy. Moreover, the policy implementation and new procedures were extensively promulgated by our communication plan to ensure all out staff members are aware of the importance of conducting a risk assessment and where to get more information or training. The RA course was well received with participation from at least one staff member from each scientific branch. Of the students completing the course, 96% indicated in the survey that they would recommend the course to others and the same number said they would apply what they learned to their laboratory work. Some concepts in the course were considered new, perhaps even controversial, such as inherent and residual risk. The application of the concepts, however, proved fairly straight forward when presented in class and when applied in the conduct of the risk assessments themselves

CONCLUSIONS

The main elements of a risk management program have been implemented at CDC, to include providing the right tools to laboratory staff to conduct a risk assessment, providing clear policy guidelines, and properly communicating the changes to our lab staff and leadership. As we strive for continual improvement of our safety program and analyze the data obtained so far a more proactive safety posture can be achieved. As illustrated below (Fig. 6) risk assessment is presented as a continuous process of incorporating information into the risk analysis cycle.

Figure 5. Risk assessment depicted as a continuous cyclical process