Welcome to the training Module 2.2 for the SHIC Rapid Response to Emerging Diseases program. In Module 1.1, you were given a brief overview of the program, including the roles and responsibilities of being an Investigator. In Module 1.2, you were introduced to fundamental concepts involved in conducting an epidemiological investigation. Module 2.1 walked you through the Investigation Phase, using the concepts from Module 1.2 to conduct an investigation interview. Finally, Module 2.2 will walk you through the Post-Investigation Phase, including assessing risk associated with each risk event and reporting findings.
Module 2.2 addresses the **Post-Investigation Phase**. By the end of this module, you will be able to determine risk of pathogen entry for each risk event. This will include assessing whether any given risk event is of low, medium, or high risk of being responsible for pathogen entry into the herd. You will then use the information collected in the Investigation Form to compile standardized reports, including an Executive Summary and a Summary Report. As stated in Module 1.1, the Executive Summary will be due within 2 days of the investigation interview and the Summary Report will be due within 11 days of the investigation interview.
After going through the Pre-Investigation Phase and the Investigation Phase, you will now walk through the Post-Investigation Phase. The Post-Investigation Phase primarily deals with turning in the Investigation Form, Executive Summary, and Summary Report. However, in order to construct any of these documents, you must know how to assess risk of pathogen entry for each risk event.
Therefore, this module will begin with determining risk of pathogen entry for each risk event.
In the context of a case investigation, risk assessment is the subjective rating of the likelihood that a certain risk event was responsible for pathogen entry into a herd. A risk event can be rated as either low, medium, or high risk by an RRC Investigator. For example, the entry of gilts might be given a “low” risk score, while the removal of cull sows might be given a “high” risk score. It is important to remember that risk assessment is a comprehensive assessment of the series of failures required for pathogen entry into the herd. This means that every piece of evidence gathered during the investigation must be taken into consideration when assessing risk, whether that is the age of the barn, the absence of the farm manager on a certain day, the weather, or something else.
The RRC Investigator’s risk assessment will be the first insight into how an emerging or transboundary disease pathogen is spreading between herds. As each RRC Investigator returns the Executive Summary and Summary Report into the RRC Coordinator, the RRC Coordinator will compile the information and look for patterns or similarities between cases. Therefore, it will be of vital importance that the risk assessment process is recorded and standardized effectively. You should keep this in mind as you move through the Post-Investigation Phase and remember that you will have to substantiate your risk assessment with accurate information.
As a reminder, there will be three different forms to turn into the RRC Coordinator, the Investigation Form, the Executive Summary, and the Summary Report. The Investigation Form was introduced in Module 2.1 and the Executive Summary and Summary Report will be covered in this module.

In the Executive Summary, the RRC Investigator will be required to report risk on high risk events only. The Executive Summary requires a final report on events considered high risk during the investigation within 2 days of the investigation interview.

In the Summary Report, the RRC Investigator will be required to report risk on all risk events. The Summary Report requires a final report on every risk event in the Investigation Form within 11 days of the investigation interview.
In order to assess risk of pathogen entry onto a farm, it is essential that you understand each of the failures required for a pathogen to enter herd. Assessing risk is assessing the likelihood that all of these failures occurred. As a review, remember that Failure #1 occurs when a carrying agent is contaminated or infected with a pathogen. This happens off-site at a pathogen source, whether that is a feed mill, truck wash, or another swine site. Failure #2 occurs when there is a failure to mitigate the contamination or infection of that carrying agent. This event is highly associated with ineffective biosecurity procedures. The next step is for the risk event to occur, meaning that the carrying agents, associated with the risk event, enters the premises. And the final failure, Failure #3, occurs when the pathogen gets from the carrying agent to the pigs in the herd. This can either be through direct contact—from pig to pig, for example. Or a secondary carrying agent can act as an intermediary, bringing a pathogen from the carrying agent to the pigs in the herd. This might happen if an on-farm employee steps on a contaminated trailer and then interacts with the pigs in the herd. Remember that if one of these failures does not occur, then a herd will not become infected with a pathogen.
As a quick example, consider an on-farm employee that works with pathogen positive pigs at another swine premises. Failure #1 occurs because the employee is contaminated. If that on-farm employee re enters the facilities without showering Failure #2 will likely have occurred. An Investigator may then find that the employee entered or reentered the barn 36x times during the investigation period. Finally, if that on-farm employee works with the pigs in the barn, then the carrying agent has direct contact with the pigs in the herd. Remember though, that if the on-farm employee did not work with a pathogen positive pig, the herd may not be exposed to the pathogen. If the on-farm employee had complied with effective biosecurity procedures, the herd may not have been exposed to the pathogen. And if the on-farm employee had not had contact with the pigs in the herd, the herd may not have been exposed to the pathogen. Keep this process in mind when assessing risk.
This module will characterize a high risk event, a medium risk event, and a low risk event with examples so that you will be able to recognize them during the investigation process.

A high risk event is defined as an event in which all three failures likely occurred. First, the carrying agent associated with that risk event is contaminated or infected with a pathogen. Second, the contamination or infection was not mitigated before entering the premises. Third, the contaminated or infected carrying agent enters the premises. And finally, the contaminated or infected carrying agent has access to pigs in the herd. If it is likely that all three of these failures occurred, then the risk event will be considered a high risk event.

Although there is no definitive way to prove that each of the failures occurred, certain pieces of evidence will provide a strong foundation for that assessment. It is the job of the RRC Investigator to gather that evidence and synthesize a strong justification for why a failure either did or did not occur.
Strength of Evidence is a type of evidence that support the conviction that each failure occurred for a given risk event. The first bucket of strong evidence is geographical proximity. Geographical proximity should be considered when a positive farm is within 5 miles of the investigated farm. Maps found in the Investigation Form can be very valuable when assessing geographic proximity. This is important for risk events such as Air and Water Entry, as well as Insect/Other Animals.

The second bucket of strong evidence is the timing and location of the first clinical signs. Take careful note during the investigation to identify whether any risk events have a strong relationship to the timing or location of the first clinical signs.

The third bucket of strong evidence is any operational connections between the investigated farm and a positive farm. Whether that is a shared semen courier, a shared truck wash, a shared veterinarian, or shared on-farm employee, these operational connections should be noted and considered.
Another factor that may contribute towards justifying a high risk event is the frequency of a risk event. The more frequently a risk event occurs, the more likely a failure will occur. Consider the example. What is the relative risk of a risk event that only occurs once with a 50% chance of causing an outbreak verses a risk event that occurs fifty times with a 1% chance of causing an outbreak? The relative risk is equivalent. It is because of this that frequency should be taken into account when substantiating claims of a high risk event. That being said, it only takes a single entry into the barn to cause an outbreak in a herd.
When working through the Investigation Form, RRC Investigators will find that “Unknown” is a popular answer choice. Although context is always important, remember that unknown variables are high risk. Consider the example in which an unknown party is contracted to haul cull sows. If the producer does not know who else the third party hauls for, this should be considered a high risk practice. When coming across unknown variables during the investigation interview, remember to include them in the “Follow-Up” section of the summary report.
Some indicators for medium risk events include if there is no single piece of resounding evidence to push the investigator one way or the other. The information collected during the investigation may support that one or two of the failures may have occurred, but that it is unlikely that all three failures occurred. Similarly, there may be many unknown variables for an otherwise low risk event. Given the a comprehensive understanding of the investigation and the context, unknown variables may push a low risk event to a medium risk event.
Finally, a low risk event is an event in which at least one failure probably did not occur. Indicators of a low risk event include no strength of evidence and if the carrying agent does not enter the barn or come in contact with the animals. Keep in mind that a carrying agent may pass on the pathogen to a secondary carrying agent which could enter the barns. If there is little chance that that happened, you may be looking at a low risk event.
When assessing risk, there will be a section in the Investigation Form/Summary Report that will provide a list of considerations to note while determining the likelihood of each failure. These considerations are tailored for each risk event and address each failure in the series of failures, as well as the types of evidence that might be associated with that risk event. Example considerations are included in the slide for the Semen Delivery risk events. When considering Failure #1, you should consider the health status of swine sites to which the carrying agents were exposed as well as regional swine density. When considering Failure #2, you should consider whether the entry of the carrying agents is delayed until test results are received and whether semen biosecurity procedures are effective and complied with. When considering Failure #3, you should consider whether the carrying agents had the opportunity to contact the swine and the involvement of a possible secondary carrying agent. Strength of Evidence associated with Semen Entry may include the timing/location of the first clinical sign of inseminated animals as well as possible operational connections with farms infected by the same pathogen.
The next few slides will walk you through examples of a high risk event, a medium risk event, and a low risk event.

In the high risk event example, RRC members will look at the risk event observations associated with cull sow removal. Failure #1 can be seen in the first observation, the hauling of cull sows is done by a third party who hauls other pigs and there is no information about the health status of these farms. Failure #2 can be substantiated by the fact that the hauler washes his truck at his house and there is no information on wash procedures or auditing protocol. Furthermore, the hallway that gilts use to enter the barn is the same as the hallway that culls use to exit the barn. This hallway is not washed between loads. The risk event occurred 3 times during the investigation period and due to the nature of the carrying agent, there is reason to believe that failure #3 occurred.

Because there is reason to believe that each of the failures occurred, this is a high risk event.
In some cases, a RRC Investigator may discover a specific type of high risk event called a “smoking gun”. “Smoking gun” events are events in which the circumstances align such that the evidence strongly suggests that a specific risk event is responsible for pathogen entry into the herd. Often, smoking guns are substantiated by geographical proximity, operational connections, or the timing and location of the first clinical signs. An example of a smoking gun event is included above.

Failure #1 may have occurred because the investigated farm has reason to believe that the repair personnel visited other swine sites and may not have had proper downtime. Failure #2 may have occurred because the repair personnel did not shower in and out of the facilities. Failure #3 occurred because the repair personnel entered the barn and came in contact with the pigs 3 days in a row.

However, this is a smoking gun because the broader story enumerated on powerful strength of evidence. In addition to all of the possible failures, the farm manager was not present on the days of repair to oversee biosecurity procedures AND the sows that exhibited the first clinical signs were located in the row where the repairs were done AND two days after the repair event, the first clinical signs were recognized. In this situation, the timing and location of the clinical signs played a large role in the
investigation.

Although every high risk event will not be a smoking gun, Investigators should be aware that they may find this type of pointed evidence.
“Feed or Feed Ingredients Delivered to the Farm” is used as an example of a medium risk event. Failure #1 may have occurred because the investigated farm does not know which other premises the third party feed hauler delivers to. However, the farm manager or herd veterinarian may know that no other farms receiving feed from the same feed mill have had outbreaks. Failure #2 may occur at the truck wash, because the truck wash procedures are unknown. This failure is substantiated by the fact that there is no downtime requirements for feed trucks AND feed truck drivers are not required to wear disposable boots. The risk event occurred 8x during the investigation period, but there is no real substantiation for Failure #3. If there was evidence suggesting that the feed itself was contaminated, this may be a high risk event. If there were fewer unknown variables, this may be a low risk event.
A low risk event will be demonstrated using Semen Entry. Since all boars are naïve to the pathogen and the health status of the swine sites that the courier comes in contact with and the boar stud, are known to be negative, it is unlikely that Failure #1 occurred. The on-farm employee takes necessary care to follow effective biosecurity procedures when returning to the facility and the semen packaging is effectively removed and disinfected, meaning that Failure #2 may not have occurred. Despite the fact that one of the possible carrying agents (semen) comes in direct contact with pigs in the herd, no further resounding evidence of other failures should lead you to consider this a low risk event.
After walking through the steps of the risk assessment process, this module will guide you through the Post-Investigation Phase. That is, applying knowledge collected during the Investigation Phase to write the Executive Summary and Summary Report. Remember that risk assessment will be crucial to the creation and completion of both reports.

### MODULE 2.2
#### Learning Objectives

- **RRC Members will be able to:**
  - Determine risk of pathogen entry into herd per risk event on outbreak farm
  - Apply knowledge collected during Investigation Phase in the **Investigation Form** to compile a standardized reports:
    - **Executive Summary** (within 2 days of investigation interview)
    - **Summary Report** (within 11 days of investigation interview)
Take a moment to look at the Post-Investigation Phase checklist. Before writing any reports, RRC Investigators must send the RRC Case Coordinator the completed Investigation Form, including answers to all numbered questions, updated maps, and the operational connections summary table.
The Investigation Form, the form that the RRC Investigator fills out during the investigation interview, must be scanned or copied and sent to the RRC Coordinator with all numbered questions and tables completed. This means that observations and risk assessment need not be included or completed. These will be necessary in the Summary Report, which uses the same template as the Investigation Form. In addition, premises maps and surrounding area maps must be updated with names and locations of swine sites within a 5-mile radius and other relevant information. If handwritten, each page must be clearly photographed or photocopied. If typed, the form can be emailed.
The final section of the Investigation Form includes an Operational Connections Summary. In order to complete the Investigation Form, the RRC Investigator must compile the known operational connections to other positive swine or swine related premises for each individual risk event and provide supporting evidence of the connection in the Observations column. In this example, Hoth Sow is a sow farm with a Semen Delivery operational connection. The farm name, Hoth Sow, was entered into the table, as well as the fact that a semen courier delivers to both Hoth Sow and the farm under investigation. The fact that the delivery was made to Hoth Sow prior to the investigation farm is also entered. The RRC Investigator should go through this process for each risk event.
Both the Investigation Form and the Executive Summary are due within two days of the investigation interview. So after the Investigation Form is complete and the RRC Investigator has a good handle on the contents of the investigation, the RRC Investigator can begin working on the Executive Summary.
The Executive Summary is a 1 page template that will provide SHIC with a brief overview of the most fundamental points of the investigation. Investigators will be required to fill information as prompted. This form will be turned in 5 days post-SHIC First Point of Contact or 2 days post investigation interview and will allow for a quick turnaround between investigation and comprehensive outbreak analysis. The following slides will give you a brief overview of each section of the Executive Summary.
The Introduction to the Executive Summary includes basic information about the actual investigation. This includes, the day that the investigation interview took place, the investigation period used during the investigation, and the people present at the investigation.
The Characteristics of Premises section details basic information taken directly from Investigation Form, including the name of the site, the name of the production system, the inventory, and so fourth.
The Description of the Current Outbreak section in the Executive Summary is a description of the information gathered in Description of the Current Outbreak section in the Investigation Form. It will ask RRC Investigators to characterize the first clinical signs and patterns of spread as well as diagnostic information and the date of the first clinical signs. All RRC Investigators will have to do is transcribe information from the Investigation Form to the Executive Summary.
The fourth section of the Executive Summary includes a table that summarizes both positive farms within a 5-mile radius and connections with positive operations. A brief summary of connections to positive farms will allow SHIC to quickly sort through any commonalities between cases. Pathogen positive farms that have connections to the case investigation and were discussed during the investigation interview should be placed and characterized in the Executive Summary table.
The final section of the Executive Summary is the Events Rated as High likelihood of being responsible for pathogen introduction into the herd. In the Executive Summary, the RRC Investigator is only responsible for reporting on events that were rated as having a high likelihood of bringing the pathogen into the herd. There is no minimum or maximum number of events required. If an event is assessed as a high risk event, it should be included. An important part of this section is Key Observations associated with that risk event. RRC Investigators will be required to substantiate high risk ratings with observations supporting that assessment.
After turning in the Investigation Form and Executive Summary to the RRC Coordinator, RRC Investigators will have 11 days post-investigation interview to complete the Summary Report.
The Investigation Form serves as the basis for the Summary Report and should be used as a template for the Summary Report. However, the Summary Report differs from the Investigation Form because the Summary Report includes a complete documentation of the RRC Investigator’s observations for each risk event, a risk assessment for all risk events (not just high risk events), a brief justification of each risk assessment, follow-up questions, and possible biosecurity recommendations. The Summary Report also includes a written narrative of the investigation findings. Due to the amount of information required in the Summary Report, RRC Investigators should complete this portion on the computer, where the template will adjust to fit the amount information included.
Observations should be described for each section of questions in the Investigation Form. For example, the Semen Delivery risk event has a section for observations on Characteristics of the Boar Stud and Surrounding Area, the Boar Stud Health Status, and Semen Delivery Practices. These observations are expected to include additional information discovered during the investigation that is in addition to the information captured by the closed-ended questions. The Observation sections allow RRC Investigators to piece together the narrative of events associated with each risk event.
Remember the RRC Investigator is telling a story that should address each of the failures in the series of failures required for pathogen entry into the herd. In addition to providing the report with context, this section also substantiates and provides support for risk assessment ratings. For example, under Semen Delivery Practices, an RRC Investigator might note that the semen packaging is not disinfected prior to entering the barn. This may lead to Failure #2. The Investigator might also note that neither the farm manager, nor herd veterinarian know where else semen courier delivers semen to before investigation site. Farm A and Farm B are both on courier’s route and are positive for the pathogen. A completed example of a Summary Report is included in your resources packet.
In the Summary Report, RRC Investigators will be required to rate every risk event as low, medium, or high.
Remember that after assessing each risk event that you will have to justify it with observations. The justification should address each failure in the series of failures required for pathogen entry into the herd and strength of evidence. When justifying a risk assessment, consult the Considerations found listed below each Risk Assessment section.
Finally, RRC Investigators may include follow-up and/or biosecurity recommendations. Follow-Up statements are the next steps that a producer or investigator could take to clarify the route of pathogen entry into the herd. Follow-up may not be necessary, depending on the risk event, but include if necessary. Using Semen Delivery as an example, one might need to determine the health status of the boar stud. Answering follow up questions may shed some light on the risk assessment.
Biosecurity recommendations include realistic and implementable biosecurity improvements that may prevent future pathogen entry. Once again, this is not required, but if the RRC Investigator has solid recommendations, they should be included. An example might be suggesting disinfecting semen packaging prior to barn entry.
After the Summary Report is completed and returned to the RRC Case Coordinator, the RRC Investigator will have finished his or her duties as an Investigator. The case will be closed.
Thank you for participating in the Rapid Response to Emerging and Transboundary Disease Program. You will be required to complete a short quiz as evidence of your training. If you have any further questions, please reference your resource packet or contact RRC@iastate.edu.