CCAC REPORTABLE ANIMAL WELFARE INCIDENTS

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The following is a selection of frequently asked questions (and their respective answers) concerning CCAC reportable animal welfare incidents, based on the *CCAC policy: Certification of ethical animal care and use programs*.

1.   What constitutes a CCAC reportable animal welfare incident?

A CCAC reportable animal welfare incident refers to one of the following:

a)   an event that leads to significant[1] mortality[2] levels of research, teaching, or testing animals, such as:

- catastrophic failure of critical life support systems or its components (e.g., malfunction of power supply, HVAC, pumps, filters, watering system, alarms, sensors, call-out systems, etc.);

- disregard of, or unintended failure (human error) to follow practices or procedures (e.g., not following approved standard operating procedures or other established processes, miscommunication, etc.); or

- any other cause of significant mortality levels such as adverse outcomes or unforeseen circumstances;

OR

b)   serious or continuous noncompliance with CCAC standards that leads to the suspension by the animal care committee or the institution of an animal-based activity threatening animal health or welfare.

Reporting Requirement

If potential mortality levels associated with described procedures are **outlined and quantified** in an approved protocol and the actual observed levels are an additional 20% or more above this baseline, they would be considered reportable. The potential mortality levels should be justified in the protocol based on commonly recognized ranges of mortality, scientific literature, shared experience, or industry standards. Potential mortality levels outlined and quantified in the "intervention points" or "humane endpoints" section of the protocol would also be included in the baseline, as would the risk of mortality associated with pilot studies.

If potential mortality levels associated with described procedures are **not outlined** in an approved protocol, the baseline is zero and actual observed levels would be considered reportable when 20% or more of animals are affected. If the number of animals is below 10, then 2 or more animals affected is considered significant and reportable (see Question 13).

See Figure 1 for scenarios where incidents would be considered significant and reportable to the CCAC. **If you are unsure of whether an event should be reported, please contact the CCAC as promptly as possible.**

The *CCAC Reportable Animal Welfare Incident Initial Notification Form* and the *CCAC Reportable Animal Welfare Incident Form* should be completed and signed by the animal care committee chair or the attending veterinarian (or a delegate) and sent to the CCAC. A copy should also be forwarded to the senior administrator responsible for the ethical animal care and use program at the institution.

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[1] Significant is relative to:
   a) The total number of animals by species, per specific project component/objective within an approved protocol on-site at the time of the incident, if the components/objectives are independent and not interrelated (e.g., component B is not contingent on component A); or
   b) The total number of animals by species within an approved protocol on-site at the time of the incident, if there is only one component/objective in the study, or if the components/objectives are dependent and conditional to one another. This also includes holding and breeding protocols.

[2] Mortality: see Questions 7 and 8 for more information on mortality.

SCENARIO 1: The protocol includes multiple independent and not interrelated project components or objectives (e.g., component B is not contingent on component A)

Was a baseline mortality level approved for **each component or objective?**

YES

NO

The CCAC would consider significant and reportable:

Any mortality levels of 20% or more above the expected and approved baseline of the total number of animals by species, per specific project component or objective in the approved animal use protocol, on-site at the time of the incident

The CCAC would consider significant and reportable:

Any mortality levels of 20% or more of the total number of animals by species, per specific project component or objective in the approved animal use protocol, on-site at the time of the incident

SCENARIO 2: The protocol includes only one distinct project component or objective OR multiple components that are dependent and conditional on one another

Was a baseline mortality level approved for **the full protocol?**

YES

NO

The CCAC would consider significant and reportable:

Any mortality levels of 20% or more above the expected and approved baseline of the total number of animals by species in the full protocol, on-site at the time of the incident

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Any mortality levels of 20% or more of the total number of animals by species in the full protocol, on-site at the time of the incident
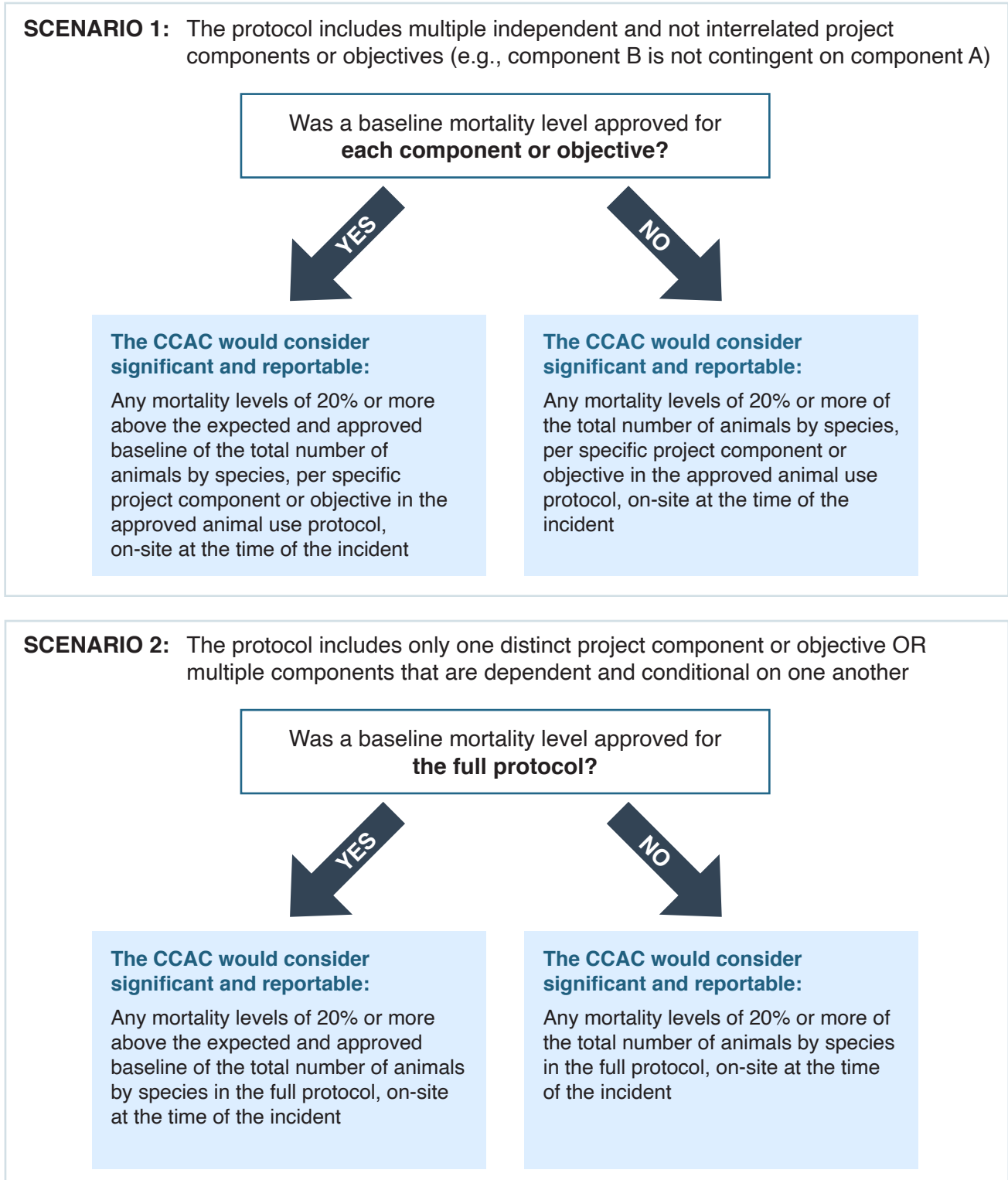
Figure 1   Scenarios in which incidents are considered significant and reportable to the CCAC.

2. **Institutions are required to notify the CCAC of a reportable animal welfare incident within 14 days (2 weeks) of occurrence. Why 14 days and not longer?**

The 14-day notification timeframe was selected for a number of reasons:

- it allows the CCAC the ability to intervene through a special visit to the institution if animals are still at risk or safeguards to prevent reoccurrence are not in place;

- it allows time for the institutional animal care committee chair to be informed and preliminary information to be collected; and

- it aligns with similar requirements of other international systems of oversight (e.g., Office of Laboratory Animal Welfare).

Notification can be done either by completing and sending the *CCAC Reportable Animal Welfare Incident Initial Notification Form* (see Question 3) or the *CCAC Reportable Animal Welfare Incident Form*, or by contacting the CCAC (613-238-4031 ext. 259; rawi@ccac.ca) and submitting a *CCAC Reportable Animal Welfare Incident Form* shortly thereafter.

3. **What is the *CCAC Reportable Animal Welfare Incident Initial Notification Form*?**

This form can be used to notify the CCAC of a reportable animal welfare incident within 14 days of occurrence before the institution has had time to fully investigate or resolve the issue. Initial notification within 14 days can also be made by contacting the CCAC (613-238-4031 ext. 259; rawi@ccac.ca). The form allows the CCAC to assess if animals are still at risk and if appropriate safeguards to prevent reoccurrence are in place.

4. **Who is responsible for notifying the CCAC of a reportable animal welfare incident?**

Once an incident has been discovered, the institution's incident reporting process should ensure that the attending veterinarian is informed without delay. The animal care committee chair and the attending veterinarian will confirm if the incident has reached the threshold of a CCAC reportable animal welfare incident, in which case the chair, the attending veterinarian, or a delegate, should notify the CCAC within 14 days of the incident. It is not necessary for the senior administrator responsible for the ethical animal care and use program to notify the CCAC.

5. **Should I wait for our institutional animal care committee to review the reportable animal welfare incident or for its full resolution before notifying or reporting it to the CCAC?**

No, the CCAC must be notified of all CCAC reportable animal welfare incidents within 14 days, whether they are resolved or not. The animal care committee chair and the attending veterinarian should be informed without delay, and the institution (either the animal care committee chair, the attending veterinarian, or a delegate) should contact the CCAC within 14 days of the incident with as much preliminary information as possible. While a review by the animal care committee following an incident would be expected, it may take some time to coordinate and could delay the reporting. Furthermore, resolution of deficiencies may take much longer than 14 days (e.g., equipment replacement, etc.); it should be part of the follow-up reporting but must not delay the initial notification to the CCAC.

6. Do cumulative mortality events have to be reported?

At present, only "isolated" reportable animal welfare incidents must be reported. Isolated means the event unfolds within a week. Cumulative mortality stretching over more than a week is not currently reportable if the "significant" threshold for an isolated event is not surpassed; however, institutions should make every effort to track these events. The CCAC will be revisiting this question by 2024.

7. What is included in mortality?

Animals that are euthanized when they reach humane intervention points and animals that are found dead should be included in mortality.

8. What is not included in mortality?

For the purpose of a CCAC reportable animal welfare incident, excess healthy animals that are euthanized, and all animals euthanized at the end of the study (when reaching scientific endpoints) should not be included in mortality.

9. Why are we being encouraged to quantify risk?

Animal care committees grant informed consent for the use of animals in research, teaching, and testing on behalf of the institution and the animals. Consequently, they should be aware of all risks to the health and welfare of animals related to their use in science. Risk can emanate from procedures done on animals, husbandry practices, transportation, captivity, or other sources.

Quantifying potential mortality is an essential component of assessing the impact of science on animals. Once animal care committees approve an acceptable level of mortality, it forms a baseline above which an additional 20% mortality is reportable. If the principal investigator has not quantified potential mortality and the animal care committee has not approved an acceptable level, the baseline is zero. For example, high mortality levels are common in the early growth stages of certain fish species, despite the best efforts of husbandry staff and research teams. This "expected" mortality, once approved by the animal care committee, would be part of the baseline.

10. What exactly is meant by "the total number of animals by species, per specific project component or objective, per approved protocol, on-site at the time of the incident"?

When determining if an animal welfare incident is significant and must be reported to the CCAC, institutions should first establish if protocols related to the incident have multiple project components or objectives. If a protocol describes multiple research objectives or components that are fully independent of each other, then the significance of the incident would be based on the total number of animals by species, per specific project component or objective, on-site at the time of the incident (see examples below).

If a research project includes components or objectives that are interrelated and conditional on each other (or if only one component or objective is described as in the case of a holding or breeding protocol), then the

significance of the incident would be based on the total number of animals by species in the full protocol, on-site at the time of the incident.

Example 1: A protocol was approved for the use of 1,080 fish. The project assesses the feasibility of wreckfish as a landlocked aquaculture species and includes three experiments: 1) feed conversion performance; 2) disease resistance; and 3) temperature preference. When the 1,080 fish arrived on site, they were allocated in equal numbers into nine tanks, for a total of 120 fish per tank and 360 fish for each of the 3 projects. Due to a calculation error, one of the tanks in the disease resistance experiment was challenged with 100x the approved amount of bacteria. Of the 120 fish in the affected tank, all died within 24 hours. None of the fish in the other tanks died. Is this a CCAC reportable animal welfare incident?

In this case, the "significance" of the 120 dead fish should be based on the total number of fish on-site for the disease resistance component (3 tanks x 120 fish/tank = 360 fish): 120 out of 360 fish for a 30% mortality level. The expected baseline mortality risk was set at 8% in the protocol for the disease resistance objective. Therefore, this mortality event is reportable because it is ≥20% above the approved risk (reportable if ≥28% mortality).

Example 2: A protocol was approved for the use of 600 mice. One specific project in that protocol has a Category of Invasiveness D and includes the injection of 64 mice with different doses of an infectious agent. The protocol doesn't indicate any baseline mortality; however, the clinical manifestations and humane intervention points are described.

- At day two post-injection, six mice had clinical cases opened for signs of mild abdominal respiration and decreased activity.

- At day three post-injection, eleven mice were found dead by the technician and six were recommended to be euthanized immediately by the veterinarian because they had reached humane intervention points.

- At day 10, all remaining mice were euthanized as the experiment ended.

Is this a CCAC reportable animal welfare incident?

If the specific project is independent of other projects approved in the protocol, if the mortality baseline is zero (no mortality level approved by the animal care committee), and if all 64 animals are on-site at the time of the incident, then this incident is **reportable** because mortality exceeded 20% (17/64= 27%). Out of 64 mice in this experimental group, 17 were either found dead or expressed clinical signs that justified euthanasia.

If the specific project is dependent on or associated with other projects approved in the protocol, if the mortality baseline is zero (no mortality level approved by the animal care committee), and if all 600 animals are on-site at the time of the incident, then this incident is **not reportable** because mortality did not exceed 20% (17/600= 3%). Out of 600 mice in this protocol, 17 were either found dead or expressed clinical signs that justified euthanasia.

11. Who should determine what reasonable mortality baselines are, and when should this be done?

At present, there is no CCAC requirement to determine and approve mortality baselines. However, if potential mortality is not quantified, the baseline is zero, and any mortality event of 20% or more is reportable. Protocol authors are strongly encouraged to work with veterinarians, other animal care personnel and animal care committees to determine reasonable baselines in an effort to better understand the impact of science on animals, and reduce the number of reportable animal welfare incidents. Baselines should be determined based on commonly recognized ranges of mortality for similar procedures, scientific literature, shared experience, or industry standards.

Animal care committees are ultimately responsible for approving these baselines, and are encouraged to add one or more questions to the animal use protocol to solicit reasonable baselines.

Baselines can be approved when a new protocol is submitted or at the time of protocol renewal. For protocols already approved but that have yet to be renewed (no baseline approved yet), a reasonable baseline can be retroactively determined and approved by the animal care committee in case of a mortality event.

Regardless of whether protocol authors quantify potential mortality or not, retroactive approval of baselines will not be permitted after **June 1, 2023**.

12. Who should determine if components of a project are independent or interrelated?

Animal use protocols comprising multiple project objectives or components should include enough detail to describe how these are either independent or interrelated. When reviewing submitted animal use protocols with multiple objectives or components, animal care committees are responsible for determining if the different parts are independent or not. Animal care committees are encouraged to add a question to the animal use protocol specifically inquiring if the protocol involves one or multiple components, and if multiple, are the components interrelated or independent?

13. How do we manage a CCAC reportable animal welfare incident related to a protocol that includes a small number of animals?

If the number of animals per independent objective is 10 or less, then 2 or more affected animals would be considered significant and reportable if there was no expected baseline mortality level (zero baseline) approved by the animal care committee. If there was an established baseline based on mortality, then a 20% mortality level or higher above the baseline would be significant and reportable.

> **Example:** A pilot study (one objective) involves four animals. The baseline approved by the animal care committee is 25% (one animal likely to die). Significance and reportability would occur if a mortality event exceeded 45% (two animals die). In this particular case, the reportability requirement is the same with or without an established baseline. If the same study with the same baseline of 25% now involved eight animals, a reportable animal welfare incident form would be required if at least four animals died or were euthanized (45% of eight animals = four animals).

14. How do we manage a CCAC reportable animal welfare incident related to a field study?

Since animals are not "on-site" in a facility at the time of an incident in the field, that criterion is replaced by "in hand" at the time of an incident, meaning animals captured/caught at one time, during one event.

Mortality events in the field are reportable if the mortality of animals "in hand" exceeds an approved mortality baseline by 20%, OR if cumulative mortality over a 7-day period exceeds an approved mortality baseline by 20%.

Note: Only animal incidents where mortality levels are 20% or more above the approved mortality baseline are reportable to the CCAC. However, there is a CCAC expectation that individual institutions have internal animal incident reporting mechanisms; institutions are responsible for identifying appropriate internal mortality or morbidity thresholds for institutional reporting.

Example 1: A research study involving caribou is described in a protocol. There is only one objective/component in this study. The mortality baseline is zero. Researchers were approved to capture up to 25 animals in an 8-week field season. They decide to capture three per week. The first week, they are only able to capture two animals, one on Tuesday and one on Thursday. Unfortunately, the animal captured on Tuesday died as a result of complications. At the time of the incident, only one animal was "in hand". As per Question 13 above, this would **not** be reportable to the CCAC. However, had they lost another animal within a seven-day period, it would be reportable if the baseline were zero, because the cumulative mortality of two animals meets the reporting threshold.

Example 2: A catch and release study involving pike is described in a protocol. There is only one objective/component in this study. The mortality baseline is 10%. The researcher was approved to capture up to 80 fish over 5 days. In the first trap set, 30 pike are caught. Five die in the trap, for an event mortality of 16%. This is **not** a CCAC reportable animal welfare incident since the "in hand" mortality was below 30% (approved baseline of 10% + 20%).

In the second trap set, 20 pike are caught, and 5 die, for an event mortality of 25%, and a cumulative mortality to date of 10 fish out of 50 (20%). This is **not** a CCAC reportable animal welfare incident since the "in hand" mortality was below 30%, and the cumulative mortality was below 30% (approved 10% baseline + 20%).

In the last trap set, 30 pike are caught and 15 die for an event mortality of 50%, and a cumulative mortality to date of 25 fish (31%). This is a reportable animal welfare incident because the "in hand" mortality was above 30% (approved 10% baseline + 20%); the cumulative mortality was also above 30%.

15. What is the process once the CCAC is notified of a reportable animal welfare incident?

As soon as the CCAC is notified of a reportable animal welfare incident, a file is created and assigned to a staff member from the Assessment and Certification program. A standardized process is used to review the information received, which includes four sequential steps:

1) Assessing if all at-risk animals are out of danger. If it is determined that the welfare of at-risk animals remains jeopardized, a special visit may be conducted and could result in a report with recommendations.

2) Assessing if appropriate safeguards to prevent reoccurrence are in place. If these have yet to be implemented, a special visit may be conducted and could result in a report with recommendations.

3) Assessing if the incident was preventable (if it is determined that all safeguards are in place and at-risk animals are out of danger). If so, then there would normally be a report with recommendations. In some cases, the CCAC Assessment and Certification Committee may decide that a special visit is still required.

4) Assessing the lines of communication. The CCAC will examine the lines of communication to ascertain if the incident was reported promptly to the attending veterinarian and the animal care committee. If this was not the case, there would normally be a report with recommendations.

If appropriate safeguards are in place, at-risk animals are out of danger, the incident was unavoidable, and the attending veterinarian and the animal care committee were informed in a timely manner, no further information would be required from the institution, and the CCAC would consider the file closed (see Appendix 1).

16. What is the process if the CCAC finds out about an unreported (past 14 days) reportable animal welfare incident?

If a CCAC reportable animal welfare incident is not reported by the institution, the CCAC could learn of it through a number of channels:

- media reports;

- whistle blowers or members of the public;

- granting agencies; or

- during an assessment visit (through discussions, documentation, etc.)

If the CCAC becomes aware of an unreported incident, a member of the Assessment and Certification team will immediately contact the institution to ascertain if the incident is, in fact, a CCAC reportable animal welfare incident. **If it is not**, no further action is needed and it can be logged in the institution's spreadsheet. **If it is**, an associate director of assessment would immediately conduct a special visit to the institution, if not already on-site.

Steps to be taken if findings include an immediate and significant threat to animal health or welfare:

- The associate director of assessment will issue a Major recommendation:

    - if the institution does not take immediate appropriate action, the associate director of assessment will propose to the CCAC Assessment and Certification Committee and the CCAC Board of Directors (through the executive director) that the institution be **decertified** as per the *CCAC policy: Certification of ethical animal care and use programs*; or

    - if the institution takes immediate and appropriate action, the associate director of assessment will include the appropriately addressed Major recommendation in a report. The report will also include additional Serious recommendations if animals are still potentially at risk, and a Serious recommendation for non-compliance with the requirement to report an incident to the CCAC within 14 days, as per the *CCAC policy: Certification of ethical animal care and use programs*.

Steps to be taken if findings indicate no immediate and significant threat to animal health or welfare:

- If animals are not potentially at risk because all proper safeguards to prevent reoccurrence are in place, the associate director of assessment will include a Serious recommendation in a report for failure to notify the CCAC of the incident.

- If there is no immediate and significant threat, but animals are still potentially at risk because not all of the proper safeguards to prevent reoccurrence have been put in place, the associate director of assessment will include Serious recommendations in a report for both the lack of required essential safeguards, and the failure to notify the CCAC of the incident.

Whether there is an immediate and significant threat to animal health and welfare or not (as described above), the institution will be given a Serious recommendation and issued a probationary certificate for non-compliance with the requirement to notify the CCAC of a reportable animal welfare incident within 14 days, as per the *CCAC policy: Certification of ethical animal care and use programs*. In addition, Serious recommendations stemming from the lack of safeguards can be included in the requirements to be fulfilled for lifting the probationary certificate. Thus, institutions must show that proper procedures are in place for notifying the CCAC of reportable animal welfare incidents within 14 days AND that all necessary safeguards are in place.

Probation can only be lifted once all Serious recommendations that lead to probation have been addressed to the satisfaction of the CCAC Assessment and Certification Committee.

Appendix 1
CCAC Reportable Animal Welfare Incident Internal Process Decision Tree