

## AMENDMENT: CHANGES IN PROCEDURES

## CHANGES IN PROCEDURES FOR AN APPROVED PROTOCOL

Current Protocol Registry Number:	
Project Title:	Click here to enter text.

## **1. PRINCIPAL INVESTIGATOR INFORMATION**

Principal Investigator: Click here to enter text., Click here to enter text.

Campus Box: Click here to enter text.

Position/Title: Click here to enter text.

Department/College: Click here to enter text.

Office/Cell Phone #:

Email Address: Click here to enter text.

This application is used to request changes in animal species, number, or methods and procedures associated with the animal use protocol specified above. It is also used to request a change in the Principal Investigator (PI) responsible for work under that protocol.

Indicate the purpose(s) of this request by checking the box(es) that apply. If your revisions are extensive, you may be asked to submit a new protocol.

Animal subjects (species, strain, or animal number) [Costs Costion 2]

Animal subjects (species, strain, or animal number) [Go to <u>section 2]</u>
Location (building, room) for housing, surgery, or non-surgical procedures. [Go to Section 3]
Nonsurgical procedure or treatment. [Go <u>to Sections 4</u> , <u>6</u> , <u>7</u> ]
Surgery (survival, non-survival) or intraoperative procedure. [Go to <u>Sections 5</u> , <u>6</u> , <u>7</u> ]
Intraoperative, post-surgical, or post-procedural care and monitoring. [Go to <u>Sections 8 A,B,C</u> ]
Humane endpoints. [Go to <u>Section 8 D</u> ]
Use of hazardous agents (biological, chemical, radiological, laser). [Go to <u>Section 9</u> ]
Method of euthanasia. [Go to <u>Section 10</u> ]
Change of Principal Investigator or Principal Investigator animal handling role. [Go to Section 11]
Other change in animal use activity. [Go to <u>Section 12</u> ]

## 2. CHANGE IN ANIMAL SPECIES NUMBER

To add additional species, click on the + at the end of each box.



SPECIES	NUMBER CURRENTLY APPROVED	ADD OR DELETE	NUMBER TO BE ADDED / DELETED
Click here to enter text.		🗌 ADD 🗌 DELETE	
Click here to enter text.		🗌 ADD 🗌 DELETE	
Click here to enter text.		🗌 ADD 🗌 DELETE	
Click here to enter text.		🗌 ADD 🗌 DELETE	
Click here to enter text.		🗌 ADD 🗌 DELETE	

#### 2.A. JUSTIFICATION FOR ADDED SPECIES

Address each added species individually.

To add additional species, click on the + at the end of each box.

SPECIES	Click here to enter text.					
This addition	This additional species was selected for the study because of the following attributes (select all that					
apply):						
	A large database exists allowing comparisons with previous data.					
Explain:	Click here to enter text.					
	The anatomy or physiology is uniquely suited to the study proposed.					
Explain:	Click here to enter text.					
	The lowest species on the phylogenetic scale that is suitable for the proposed study.					
Explain:	Click here to enter text.					
	Other attributes:					
Explain:	Click here to enter text.					

#### **2.B.** JUSTIFICATION FOR ADDITIONAL ANIMALS

Address each species individually.

To add additional species, click on the + at the end of each box.

**SPECIES:** Click here to enter text.

 The number of additional animals requested for this protocol is based on the following (select all that apply):

 The number needed to offset an earlier underestimate of animal requirements.

 Explain:
 Click here to enter text.

 The number required to populate new or expanded experimental groups.

 Explain:
 Click here to enter text.

A new or revised statistical estimate of the number required to achieve statistical significance.
 Explain: Click here to enter text.
 A new or revised estimate of the number necessary to achieve the goals of the study in the absence of a statistical estimate.
 Explain: Click here to enter text.

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	The number necessary to obtain additional tissue or other material for testing or analysis.		
Explain: Click here to enter text.			
The number required to provide additional technical training or practice for the number			
	trainees expected.		
Explain:	Click here to enter text.		

#### TABLE 2.C.1. POST-WEANING ANIMALS (ONLY)

To add additional species, click on the + at the end of each box.

ADULT SPECIES:	Click her	e to enter text.	AGE OR WEIGHT RANGE:		ADDITION NUMBER REQUIRED		
NUMBER OF ADD	DITIONAL	ANIMALS IN USD	A CATEGO	RIES:			
CATEGORY B: (breeding animals)			CATEGORY D: (procedures using anesthesia/analgesia)				
CATEGORY C: (non-painful procedures)			CATEGORY E: (pai without anesthes	•			
SOURCE OF THE ANIMALS:							
Note: for animals transferred from another DU protocol, provide PI name and protocol number:							
PI NAME:	PI NAME: Click here to ent		ter text.	IRBNet NUMBER:			

#### 2.C. DISTRIBUTION OF ADDITIONAL ANIMALS OVER USDA PAIN AND DISTRESS CATEGORIES.

Complete the table below.

## TABLE 2.C.A. PRE-WEANING/NEONATAL/EMBRYONIC ANIMALS (ONLY)

To add additional species, click on the + at the end of each box.

PRE-WEANING SPECIES:	Click here to enter text.	AGE OR WEIGHT RANGE:	ADDITI NUMB REQUI	ER
NUMBER OF ADL	DITIONAL ANIMALS IN US	DA CATEGO	DRIES:	
CATEGORY B: (br	eeding animals)		CATEGORY D: (procedures using anesthesia/analgesia)	
CATEGORY C: (no	on-painful procedures)		CATEGORY E: (painful pro without anesthesia/analg	
SOURCE OF THE	ANIMALS:			
Note: for animals	transferred from anothe	r DU protoc	ol, provide PI name and pro	otocol number:
PI NAME: Click here to enter		nter text.	IRBNet NUMBER:	

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## 3. CHANGE IN LOCATION FOR APPROVED ANIMAL USE ACTIVITY

ADD/DELETE:	BUILDING:	ROOM:	ASSOCIATED ANIMAL USE ACTIVITY:	SPECIES INVOLVED:
🗌 ADD	Click here	Click here to	housing > 12 hours	Click here to enter
DELETE	to enter	enter text.	housing < 12 hours	text.
	text.		survival surgery	
			non-survival surgery	
			non-surgical procedures	
			hazardous agent use	
			breeding colony	

State the reason(s) for the change(s) in location(s) for approved animal use activities: Click here to enter text.

## 4. CHANGE IN NON-SURGICAL PROCEDURE

In addition to Section 3, you will also need to fill out <u>Section 5</u> and <u>Section 6</u>.

#### 4.A. ADDED OR ALTERED NON-SURGICAL PROCEDURE(S)

4.A.1. Describe the non-surgical procedure(s) to be added to this protocol or explain how existing procedures are to be altered. If new animal groups are involved, define group sizes and specify how each group will be tested or used. If testing or use of individual animals occurs over time, define the timeline for experimental events.

#### Click here to enter text.

4.A.2 Are the added or altered procedures expected to cause pain, but for which pain-relieving anesthetics and/or analgesics will not be provided?

#### Yes No

If you selected 'YES' please complete the following:

a. Identify the treatment groups and specify the number of animals in each group that will not be provided with pain relief. Click here to enter text.

b. Detail the scientific reason that requires the withholding of anesthetics and/or analgesics for pain relief.

Click here to enter text.



#### 4.B. MONITORING AND HUMANE ENDPOINTS FOR ADDED ALTERED PROCEDURES.

4.B.1. Monitoring of animal condition will be:

as described in the approved protocol

as detailed in section 7 of this form

#### 4.B.2. Monitoring endpoints will be observed:

as described in the approved protocol

as detailed in section 7 of this form

### 4.C. DELETED PROCEDURE(S)

4.C.1. Specify any existing non-surgical procedures that should be deleted from this protocol. Click here to enter text.

## 5. CHANGE IN SURGICAL PROCEDURE

In addition to Section 5, you will also need to fill out Section 6 and Section 7.

#### 5.A. ADDED OR ALTERED SURVIVAL SURGERY PROCEDURE(S)

5.A.1. Describe the survival surgery procedure(s) to be added to this protocol or explain how existing survival surgery procedures are to be altered. If new animal groups are involved, define group sizes and specify how each group will be tested or used. If testing or use of individual animals occurs over time, define the timeline for experimental events.

Click here to enter text.

5.A.2. Will the added or altered survival surgery cause any animal to experience more than one survival surgery procedure?

no, individual animals will be exposed to only a single surgical procedure

yes, the change will cause some individual animals to be subjected to more than one survival surgery

5.A.3. Please describe how the multiple survival surgeries, including any that may have occurred prior to entering this study, are interrelated components of this protocol and why they are necessary to achieve the scientific objective.

Click here to enter text.

### 5.B. Added or Altered Non-survival Surgery Procedure(s)

5.B.1. Describe the non-survival surgery procedure(s) to be added to this protocol or explain how existing non-survival surgery procedures are to be altered. If new animal groups are involved, define group sizes and specify how each group will be tested or used. If testing or use of individual animals occurs over time prior to this non-survival procedure, define the timeline for experimental events. Click here to enter text.

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#### 5.C. MONITORING AND HUMANE ENDPOINTS FOR ADDED OR ALTERED SURGERY.

- 5.C.1. Monitoring of animal condition will be:
- as described in the approved protocol
- \_\_\_\_ as detailed in section 7 of this form

#### 5.C.2. Humane endpoints will be observed:

- as described in the approved protocol
- as detailed in section 7 of this form

#### 5.D. DELETED SURGICAL PROCEDURE(S)

5.D.1. Specify an existing survival or non-survival surgical procedures that should be deleted from this protocol.

Click here to enter text.

## 6. PURPOSE AND SCIENTIFIC BENEFIT OF ADDED OR ALTERED PROCEDURE

6.1. This section must be filled out in addition to either <u>Section 3</u> or <u>Section 4</u>. State the relationship of added procedure(s) to the purpose of the study described in <u>Section B1</u> of the approved protocol.

Click here to enter text.

6.2. State how the added procedure(s) will contribute to the scientific benefit of the study described in Section B2 of the approved protocol. Click here to enter text.

## 7. LITERATURE SEARCH FOR ALTERNATIVES TO PAINFUL PROCEDURES

This section must be filled out in addition to either <u>Section 4</u> or <u>Section 5</u>. Alternatives that decrease the potential for pain must be considered whenever potentially painful procedures are proposed, even when the use of pain-relieving drugs is planned. Please provide evidence of a literature search for suitable alternatives to each added/revised potentially painful procedure.

Date literature search was performed (day, month, year): Click here to enter a date. Years covered by the search (From – To): Click here to enter text. Keywords used in the search: Click here to enter text. Databases searched (check all that apply):

AGRICOLA
Biological /

Biological Abstracts
PubMed/MEDLINE

Web of Science Animal Welfare Information Center Other: Click here to enter text.

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TOXNET	UC Davis Guide to Bibliographic Databases for				
SciFinder Scholar	Alternatives Searching				
AltBib	Other: Click here to enter text.				
@ltWeb					
Did the literature search reveal less painful alternatives to the potentially painful procedures that are					
proposed?					
Yes No					
8. CHANGE IN ANIMAL MONITORING OR HUMANE ENDPOINTS					

8.A. CHANGE IN MONITORING DURING ANESTHESIA.			
8.A.1. This change applies to: Non-surgical procedures	Survival surgery	Non-survival	

8.A.2. Indicate below the indices, or changes therein, that will be used to monitor the depth of anesthesia and condition of the animal while under anesthesia. Note that unless specifically deleted, indices specified in the approved protocol continue to apply.

ADD	DELETE	:Respiratory rate/effort
🗌 ADD	DELETE	:Mucous membrane color
🗌 ADD	DELETE	:Body temperature
🗌 ADD	DELETE	:Oxygen saturation
🗌 ADD	DELETE	:Capillary refill time
🗌 ADD	DELETE	:Heart rate
🗌 ADD	DELETE	:Blood pressure
🗌 ADD	DELETE	:EKG
🗌 ADD	DELETE	:Reflex (specify): Click here to enter text.
🗌 ADD	DELETE	:Other (specify): Click here to enter text.
🗌 ADD	DELETE	:Other (specify): Click here to enter text.

8.A.3. For added indices, specify the frequency at which they will be recorded: Click here to enter text.

8.A.4. For deleted indices, state the reason previously approved indices will no longer be used: Click here to enter text.

8.B. CHANGE IN MONITORING DURING RECOVERY FROM ANESTHESIA		
8.B.1. This change applies to: <ul> <li>Non-surgical procedures</li> </ul>	Survival surgery	



8.B.2. Indicate below the indices or changes therein, that will be used to monitor animal condition during recovery from anesthesia. Note that unless specifically deleted, indices specified in the approved protocol continue to apply.

ADD	DELETE	:Respiratory rate/effort
🗌 ADD	DELETE	:Mucous membrane color
🗌 ADD	DELETE	:Body temperature
🗌 ADD	DELETE	:Oxygen saturation
🗌 ADD	DELETE	:Capillary refill time
🗌 ADD	DELETE	:Heart rate
🗌 ADD	DELETE	:Blood pressure
🗌 ADD	DELETE	:EKG
🗌 ADD	DELETE	:Reflex (specify): Click here to enter text.
🗌 ADD	DELETE	:Other (specify): Click here to enter text.
ADD	DELETE	:Other (specify): Click here to enter text.

8.B.3. For added indices, specify the frequency at which they will be recorded: Click here to enter text.

8.B.4. For deleted indices, state the reason previously approved indices will no longer be used: Click here to enter text.

#### **8.C.** Change in monitoring during the study until termination.

8.C.1. The change applies to:

Non-surgical procedures

Post-survival surgery

Indicate below the parameters, or changes therein, that will be used to detect pain, distress, or discomfort and promote the general well-being of animals during the course of the study. Monitoring of five or more parameters is recommended.

CHOOSE ADD or MONITORING PARAMETER DELETE		FREQUENCY OF OBSERVATION
ADD DELETE	Not eating or drinking (requires individual housing)	Click here to enter text.
ADD	Fecal and urine output (requires individual housing)	Click here to enter text.
ADD DELETE	Body weight (requires frequent weight checks)	Click here to enter text.
ADD DELETE	Behavioral change (aggression, guarding, hiding)	Click here to enter text.

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CHOOSE ADD or DELETE	MONITORING PARAMETER	FREQUENCY OF OBSERVATION
ADD DELETE	Licking, biting, scratching or shaking of procedure site	Click here to enter text.
ADD DELETE	Hair coat (ruffled fur, lack of grooming, piloerection)	Click here to enter text.
ADD DELETE	Posture or ambulation (tense, tucked-up, stiff gait)	Click here to enter text.
ADD DELETE	Activity level (restlessness, pacing, reluctance to move)	Click here to enter text.
ADD DELETE	Facial expression (eyes dull, pupils dilated, pinning of ears)	Click here to enter text.
ADD DELETE	Sweating or salivation (stressed rodents salivate excessively)	Click here to enter text.
ADD DELETE	Oculonasal discharge (rats shed reddish porphyrin pigment)	Click here to enter text.
ADD DELETE	Teeth grinding	Click here to enter text.
ADD DELETE	Other, specify: Click here to enter text.	Click here to enter text.

For each monitoring parameter that is added, indicate the action you will take if observations suggest pain, distress, or a decline in animal well-being.

Click here to enter text.

For deleted monitoring parameters, state the reason previously approved parameters will no longer be used: Click here to enter text.

#### 8.D. CHANGE IN HUMANE ENDPOINTS THAT WILL PROMPT INTERVENTION TO PREVENT CONTINUED PAIN OR DISTRESS.

#### Humane Endpoints to be Added:

From the list below, select humane endpoints to be added that are appropriate within the context of the present study for determining when intervention for humane reasons will occur. For each endpoint added, indicate the action that will be taken should the endpoint be reached.

#### TABLE 8.D.A. HUMANE ENDPOINTS

HUMANE ENDPOINT THAT WILL PROMPT ACTION AT RIGHT	VETERINARY CONSULTATION	EUTHANASIA	OTHER ACTION (DEFINE)
Infection unrelated to the protocol.			Click here to enter text.

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I	HUMANE ENDPOINT THAT WILL PROMPT ACTION AT RIGHT	VETERINARY CONSULTATION	EUTHANASIA	OTHER ACTION (DEFINE)
	Signs of moderate to severe pain or distress that was not anticipated by the study plan.			Click here to enter text.
	Body weight loss exceeding 15% of free-feeding body weight relative to an age-matched reference.			Click here to enter text.
	Mutilation of operative site or other self mutilation.			Click here to enter text.
	Neurological disorders (e.g., seizures, blindness, ataxia) that were not anticipated by the study plan.			Click here to enter text.
	Cardiopulmonary disorders (e.g. sudden weakness, vascular collapse, coma) that were not anticipated by the study plan.			Click here to enter text.
	Abnormal feeding or defecation for 48 hours (e.g., decreased feed or water intake and/or decreased fecal production that is unrelated to the study plan).			Click here to enter text.
	Non-weight bearing for 72 hours (e.g., difficulty walking, inability to maintain upright posture)			Click here to enter text.
	Other (specify): Click here to enter text.			Click here to enter text.
	Other (specify): Click here to enter text.			Click here to enter text.

#### Humane Endpoints to be Deleted:

Specify humane endpoints that you wish to have deleted from the approved protocol and explain why they are no longer necessary or appropriate for determining when intervention for humane reasons should occur. Click here to enter text.



## 9. CHANGE IN HAZARDOUS AGENT USE

#### 9.A. HAZARDOUS AGENTS

9.A.1. Indicate the nature of the change(s) and the type(s) of hazardous agent(s) affected (check all that apply):

\*Please confirm with the IBC Chair that change does not need to be reviewed by the IBC

ADD DELETE : Human cells or fluids
ADD DELETE : Active virus / bacteria / prion
ADD DELETE : Attenuated virus / bacteria
ADD DELETE : Recombinant DNA
ADD DELETE : Carcinogens / mutagens*
ADD DELETE : Toxicological agents*
ADD DELETE : Other hazardous chemicals*
ADD DELETE : Laser / irradiator / x-ray machines
ADD DELETE : Radioactive materials
ADD DELETE : Tissue fixatives (formalin, paraformaldehyde)

#### TABLE 9.A.A. HAZARDOUS AGENTS

To add additional agents, click on the + at the end of each box.

AGENT (IDENTIFY)	DOSE THE FREQUENCY OF ADMINISTRATION	ROUTE OF ADMINISTRATION	DURATION OF TREATMENT
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

#### TABLE 9.A.B. IDENTIFYING HAZARDOUS AGENTS

To add additional agents, click on the + at the end of each box.

For each added agent listed above, please address the following issues:

AGENT (identify): Click here to enter text.

The standard operating procedure (SOP) for use of the hazardous agent.

Click here to enter text.

Personnel protection precautions to be used by laboratory personnel and individuals performing animal husbandry:

Click here to enter text.

Length of time the agent remains a threat to the health of the animals or humans working with the animals:

Click here to enter text.

Duration of animal survival between exposure to the agent and euthanasia:

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#### Click here to enter text.

Means of caging and equipment decontamination:

Click here to enter text.

Method of animal waste disposal:

Click here to enter text.

Method of animal carcass disposal:

Click here to enter text.

## 10. CHANGE IN METHOD OF EUTHANASIA

#### **10.A. NATURE OF CHANGE IN EUTHANASIA**

10.A.1. Please indicate the nature of change that is requested:

Deletion of currently approved method of euthanasia from protocol

Additional method of euthanasia added to the protocol

If additional method(s) of euthanasia are added to the protocol, specify method here: Click here to enter text.

Indicate why euthanasia method to be deleted is no longer required: Click here to enter text.

## TABLE 10.A.A. GENERALLY ACCEPTABLE METHODS OF EUTHANASIA (INJECTABLE, INHALATION, PHYSICAL UNDER

#### ANESTHESIA)

Specify the method(s) of euthanasia to be added below. Use a separate line for each species to which it will apply.

NOTE: Selection of CO2 as a method of euthanasia requires all personnel listed on this protocol to complete technical training in that method.

To add additional species, click on the + at the end of each box.

SPECIES	METHOD	ANESTHETIC OR INJECTABLE AGENT/DOSE/ROUTE OF ADMINISTRATION OR TRICAINE CONCENTRATION
Click here to enter text.	<ul> <li>CO2 inhalation chamber</li> <li>Decapitation under anesthesia</li> <li>Exsanguination under anesthesia</li> <li>Inhalant anesthetic gas (no ether)</li> <li>Injectable euthanasia agent</li> <li>Tricaine (MS-222) immersion</li> </ul>	Click here to enter text.

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SPECIES	METHOD	ANESTHETIC OR INJECTABLE AGENT/DOSE/ROUTE OF ADMINISTRATION OR TRICAINE CONCENTRATION
	Tricaine (MS-222) applied to gills	

If CO2 euthanasia was selected for any species, a secondary method to ensure non-recovery is required. Please select the secondary method(s) that will be used to ensure euthanasia:

Bilateral thoracotomy Decapitation

] Tissue / organ collection.

Other method to ensure death

Specify tissues / organs: Click here to enter text.

**Specify:** Click here to enter text.

# TABLE 10.A.B. CONDITIONALLY ACCEPTABLE METHODS OF EUTHANASIA (PHYSICAL WITHOUT ANESTHESIA) To add additional species, click on the + at the end of each box.

SPECIES	METHOD	SCIENTIFIC JUSTIFICATION FR PROCEDURE WITHOUT ANESTHESIA
Click here to enter text.	<ul> <li>decapitation without</li> <li>anesthesia</li> <li>cervical dislocation without</li> <li>anesthesia</li> </ul>	Click here to enter text.

# TABLE 10.A.C. OTHER METHODS OF EUTHANASIA (CONSISTENT WITH AVMA GUIDELINES ON EUTHANASIA) To add additional species, click on the + at the end of each box.

SPECIES	METHOD	AGENT/DOSE/ROUTE OF ADMINISTRATION AS APPLICABLE
Click here to enter text.	Click here to enter text.	Click here to enter text.

# Please explain the reason for performing euthanasia by a method other than those identified above as generally or conditionally acceptable:

Click here to enter text.



## 11. CHANGE IN PRINCIPAL INVESTIGATOR

#### 11.A. CHANGE IN PRINCIPAL INVESTIGATOR (PI) RESPONSIBLE FOR PROTOCOL.

Attach a PI Agreement (Protocol Section F) executed by the new Principal Investigator. Also complete and attach a personnel qualifications form (PQF) that reflects skills, experience, and training required for the new PI's animal handling activities.

PQF is not required if a PQF that reflects appropriate skills is already on file as part of this protocol.

#### TABLE 10.A.A. PI CHANGES RESPONSIBLE FOR PROTOCOL

To add additional PI's click on the + at the end of each box.

PI CHANGE	NAME	ANIMAL HANDLING ROLE
ADD DELETE	Click here to enter text.	Click here to enter text.

#### 11.B. CHANGE IN ANIMAL HANDLING ROLE FOR PRINCIPAL INVESTIGATOR

Complete and attach an updated personnel qualifications form (PQF) that reflects skills, experience, and training required for the additional animal handling activities. (An updated PQF is not required if the PQF currently on file indicates appropriate skills for the new activities.)

#### TABLE 11.B.A. CHANGE IN ANIMAL HANDLING ROLE FOR PRINCIPAL INVESTIGATOR

To add additional Pl's, click on the + at the end of each box.

NAME	ADDITIONAL ACTIVITIES	DELETED ACTIVITIES
Click here to enter text.	Click here to enter text.	Click here to enter text.

**NOTE:** PI Agreement (Protocol Section F) and PQF (Personnel Qualifications Form) are available in the IRBNet Library

## **12.** OTHER CHANGES IN ANIMAL USE ACTIVITIES

12.1. Add the activities that are described in detail below. Click here to enter text.

12.2. Delete only those activities that are specified below. Click here to enter text.

## 12.3. State the reason(s) for the above change(s).

Click here to enter text.