

The image shows an ornate wrought-iron gate to Emory University. The gate is topped with a decorative lantern and a sign that reads "EMORY". To the right of the gate is a stone pillar with a plaque for Isaac Stiles. The plaque lists his birth and death dates, his education at Emory University, and his various roles, including Professor of Latin, English, and Moral Science, and President of Emory University. The background features a clear blue sky and bare trees.

# Overview of Recent CS/DD Form Changes

*March 13, 2024*

# In this presentation

We've covered why compliance matters, what is a Controlled Substance (CS)/Dangerous Drug (DD), ordering/receiving, and conducting an inventory in our previous webinars.

In this presentation, we will discuss recent changes to the Emory forms, as a result of lab feedback, QA/QI Reviews, and IACUC tag-alongs.



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# Thank you



ORIC has visited and talked with over 50 labs to get a better understanding of the PI/labs needs and how forms can be amended to make life easier for each Registrant.

ORIC wants to extend a special thank you to a few of the PI/labs for providing invaluable input.

Without your input we would not be able to serve you better.



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# Federal and State Regulations

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All the input we've received has been very important. Our office is here to ensure each Registrant is compliant with the federal and state regulations which require that each Registrant document the receiving, manufacturing, dispensing/administering, and destruction of controlled substances and dangerous drugs.

The forms were updated to assist each registrant in tracking the drug usage so that complete and accurate records are maintained.

While the Emory forms are not required, the information in them is required by the federal and state government. The Registrant is responsible for ensuring 100% accountability of the controlled drugs they have acquired.

# What does drug accountability look like?

## Researcher X

Drug In				Drug Out			Match
Drug Name & concentration	Initial Inventory (a)	Drug Received (b)	Total (c) (a+b=c)	Closing Inventory (d)	Dispensed/Destroyed (e)	Total (f) (d+e=f)	Difference (g) = (f-c)
Ketamine 10mg/ml	100ml	500ml	600ml	200ml	400ml	600ml	0ml
Ketamine .05mg/ml	0ml	0ml	0ml	0ml	500ml	500ml	-500ml
Ketamine/Xylazine/ Saline 1mg/2mg/mg	50ml	1000ml	1050ml	300ml	500ml	800ml	-250ml
Cocaine raw powder	10g	0g	10g	15g	0g	15g	+5g

# Form Updates

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With the regulations in mind, the ORIC team updated the forms to make them easier to use. Emory Forms are not required however, the templates incorporate all of the required elements from the applicable regulations. Any format used must meet the requirements of all pertinent regulations.

Three of the biggest updates are:

1. A new form for each unique bottle ID is no longer needed. Form 7, 11, C, D, and F may be used continuously if the drug name and strength/concentration remains the same.
2. The destruction or disposition of drug should not be documented on the dispensing form. ORIC created separate forms 4 and I for that purpose.
3. The inventory form has been updated according to regulations and updated in a way that helps to remind each Registrant that the expired and dilutions need to be counted as part as the biennial inventory. It's also required by law to note whether the inventory was done before or after business (BOB or COB).



# Why?

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Federal and State Regulations require you to be 100% accountable for the drugs you receive, manufacture, dispense/administer, and dispose of.

Did you know that every time you dilute a drug you received from your Supplier that you are “manufacturing” a new drug? You are responsible for knowing how much of the controlled drugs is in each solution. You are also responsible for inventorying the dilutions.

Disposition was removed from the dispensing forms so it's not counted as both a dispensation and a destruction. Doing so would affect the drug accountability.

# New Dangerous Drug Form Updates

Form A – Dangerous Drug Access Log (new updates help track, training and key control)

Form B – Dangerous Drug Receipt Log (updated to reflect regulation requirements in lieu of invoice/packing slip documentation)

Form C – Dangerous Drug Use Form (Updated to be used continually as long as the drug name and concentration/strength stay the same. An expiration date column was added to help ensure that registrant is not dispensing expired drugs. Disposition was removed)

Form D – Isoflurane Use Form (Updated to be used continually, track expiration dates, disposition removed)

Form E – Dangerous Drug Discrepancy and Incident Form (updated to add an incident reporting format to establish good documentation practices)

Form F – Dilution Log (Updated to be used continually as long as the drug name and concentration/strength stay the same. An expiration date column was added to help ensure that registrant is not dispensing expired drugs. Disposition was removed)

Form G & H – Meloxicam Stock Bottle and Dilution Form was developed to help Registrant track the number of punctures and expiration date.

Form I – Dangerous Drug Destruction Log (New Form was created to separate and accurately document the destruction of the drug on appropriate form. Dispositions should no longer be documented on Use Forms C, D, F)



## Sample Form C – DANGEROUS DRUG USE FORM

Note: This form is to be used to track the usage of all dangerous drug stock bottles.

Box 1: Registrant Information		
Registrant's Name: <i>Joe Smith</i>	GBP #: <i>PHRS1234567</i>	Registered Address: <i>123 Main Street, Room # C5100, Atlanta, GA, 30325</i>

Box 2: Stock Bottle Information	
Name of Substance: <i>Isoflurane</i>	Concentration/Strength: <i>100%</i>

Note: Record the total quantity of the substance to the nearest metric unit weight or the total number of units. The log balance must always match the physical balance of dangerous drug. Any discrepancies (overfill or underfill), or other circumstances that indicate significant loss or theft of dangerous drug must be promptly reported using Form E. **DO NOT RECORD DISPOSITION/DESTRUCTION OF DRUG ON THIS FORM. USE FORM I FOR DISPOSITION/DESTRUCTION**

Box 3: Current Dangerous Drug Use Log				Drug Name and Concentration/Strength: <i>Isoflurane 100%</i>			
Date	Unique Bottle ID	Expiration Date	Starting Volume/Quantity	Amount Used	Balance Remaining	Printed Name of Person who used the drug	Notes/Comments (optional)
<i>02/11/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>250 ml</i>	<i>10ml</i>	<i>240ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>02/15/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>240ml</i>	<i>20ml</i>	<i>220ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>02/19/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>220ml</i>	<i>10ml</i>	<i>210ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>02/28/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>210ml</i>	<i>30ml</i>	<i>180ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/05/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>180ml</i>	<i>50ml</i>	<i>130ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/10/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>130ml</i>	<i>40ml</i>	<i>110ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>03/11/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>110ml</i>	<i>50ml</i>	<i>60ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>03/15/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>60ml</i>	<i>30ml</i>	<i>30ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/17/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>30ml</i>	<i>30ml</i>	<i>0ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
----- <i>New Bottle</i> -----							
<i>03/18/23</i>	<i>ISO031823</i>	<i>04/01/23</i>	<i>250ml</i>	<i>150ml</i>	<i>100ml</i>	<i>Joe Smith</i>	<i>Protocol #456</i>
<i>03/30/23</i>	<i>ISO031823</i>	<i>04/01/23</i>	<i>100ml</i>	<i>80ml</i>	<i>20ml</i>	<i>Joe Smith</i>	<i>Protocol #456, remainder sent to EHSO</i>

## Sample Form F: Dangerous Drug Dilution and Use Form

Note: This form may only be used if the drug name, concentration, and total volume, created remains the same. A new form must be used if the concentration changes.

Box 1: Registrant Information				
Registrant's Name: <i>Joe Smith</i>		GA Board of Pharmacy #: <i>PHRS12345678</i>	Registered Address: <i>123 Main Street, Room #4567, Atlanta, GA, 30325</i>	
Box 2: Calculating Concentrations from Stock Bottles				
(2a)	(2b)	(2c)	(2d)	(2d)
DD Drug Name : <i>Xylazine</i>	Concentration (C): <i>1.5mg/ml</i>	Volume Added (V): <i>2ml</i>	Total Volume (TV): <i>10ml</i>	Conversion Factor (CF)* (CF=C x V/TV): <i>(1.5mg x 2ml)/10ml = 0.3mg/ml</i>
Drug Name: (diluent) <i>Bacteriostatic Saline</i>	Concentration (C): <i>1</i>	Volume Added (V): <i>8ml</i>		Conversion Factor (CF)*: (CF= V/TV): <i>(8ml/10ml) = 0.8ml</i>
Drug #3 Name(if applicable): <i>N/A</i>	Concentration (C): <i>N/A</i>	Volume Added (V): <i>N/A</i>		Conversion Factor (CF)* <i>N/A</i>
Drug #4 Name(if applicable): <i>N/A</i>	Concentration (C): <i>N/A</i>	Volume Added (V): <i>N/A</i>		Conversion Factor (CF)* <i>N/A</i>

Box 3: DD Dilution Working Bottle Information and Label	Working Bottle Unique ID: <i>varied</i>
Mixture Name: <i>Xylazine/Saline</i>	Working Bottle Expiration Date*: <i>varied</i>
Concentration of Working Dilution* (mg/ml): <i>0.3mg/ml</i>	Working Bottle 1st Puncture Date: <i>varied</i>
Total Volume (TV) : <i>10ml</i>	Date mixed and Initials of Person Mixing: <i>varied</i>
Fill in this side of Box 3. This info must be on the working bottle	This side of Box 3 varies per bottle but must be on the working bottle

Box 4: Drug Usage for Working Bottle				Drug Name and Concentration: <i>Xylazine/Saline 0.3mg/ml</i>			
Date	Unique Bottle ID	Unique Bottle ID Expiration Date	Starting volume	Volume removed	Total volume remaining (TVR)	Initials of person administering	Reason for Use
<i>04/01/23</i>	<i>XYSA040123</i>	<i>06/01/23</i>	<i>10ml</i>	<i>1ml</i>	<i>9ml</i>	<i>DB</i>	<i>Protocol 21345</i>
<i>04/03/23</i>	<i>XYSA040123</i>	<i>06/01/23</i>	<i>9ml</i>	<i>2ml</i>	<i>7ml</i>	<i>JS</i>	<i>Protocol 21345</i>
<i>04/10/23</i>	<i>XYSA040123</i>	<i>06/01/23</i>	<i>7ml</i>	<i>1ml</i>	<i>6ml</i>	<i>JS</i>	<i>Protocol 21345</i>
<i>04/15/23</i>	<i>XYSA040123</i>	<i>06/01/23</i>	<i>6ml</i>	<i>1ml</i>	<i>5ml</i>	<i>DB</i>	<i>Protocol 21345</i>
<i>04/16/23</i>	<i>XYSA040123</i>	<i>06/01/23</i>	<i>5ml</i>	<i>2ml</i>	<i>3ml</i>	<i>DB</i>	<i>Protocol 21345</i>



# New Controlled Substance Forms

Form 2 – Controlled Substance Access Log (new updates help track training, key control, and background checks)

Form 3 – Emory University Employee and Agent Screening Statement (Updated to track the background check of employees/students who have access to controlled substances)

Form 4 - Controlled Substance Destruction Log (New Form designed to properly track the documentation of destructions)

Form 5 - Controlled Substance Discrepancy and Incident Report (updated to add an incident reporting format to establish good documentation practices)

Form 6 – Controlled Substance Inventory (Updated to help Registrant properly document BOB/COB, expired drugs, dilutions)

Form 7 – Controlled Substance Use Log (Updated to be used continually as long as the drug name and concentration/strength stay the same. An expiration date column was added to help ensure that registrant is not dispensing expired drugs. Disposition was removed)

Form 8 – Order/Receipt Log for Schedule I & II Controlled Substances (updated to reflect regulation requirements in lieu of invoice/packing slip documentation & 222)

Form 9 – Receipt Log for Schedule III-V Controlled Substances (updated to reflect regulation requirements in lieu of invoice/packing slip documentation)

Form 11 – Controlled Substance Dilution Log (Updated to be used continually as long as the drug name and concentration/strength stay the same. An expiration date column was added to help ensure that registrant is not dispensing expired drugs. Disposition was removed)

Form 14 - Internal Transfer Form (Updated to align with new Emory policy 7.25. Internal transfers are now allowed but must be approved by ORIC first)

## Sample Form 6B: Controlled Substances Inventory Continued

Annual Inventory  Biennial Inventory  : Schedule III-V

Note: A Biennial inventory must be conducted once within every two years of the date of the Initial Inventory. An annual inventory is recommended. A separate inventory sheet for Schedule I & II and Schedule III - V Controlled Substances must be maintained. Stock and Working Bottles, and Expired Containers must all be counted.

Box 1: Registrant Information				
Registrant's Name: <i>Joe Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Atlanta, GA, 30325</i>		
Date of Inventory: <i>05/01/23</i>	<input checked="" type="radio"/> BOB <input type="radio"/> COB* (circle one)	Name Persons conducting Inventory	Employee #1: <i>Joe Smith</i>	Employee #2: <i>Joann Taylor</i>

Box 2: Complete Physical Inventory for ALL Schedule III – V Controlled Substance on hand at the time of inventory							
Line No.	Name of Substance	Concentration/Strength	Initial Volume/Quantity of Container	Number of Containers	Total Quantity/Volume on Hand per Concentration/Strength	Stock/Working	Active or Expired
1	<i>Ketamine</i>	<i>100 mg/ml</i>	<i>10ml</i>	3	<i>30ml</i>	<i>stock</i>	<i>active</i>
2	<i>Ketamine</i>	<i>100 mg/ml</i>	<i>10ml</i>	1	<i>10ml</i>	<i>stock</i>	<i>expired</i>
3	<i>Ketamine/Xylazine/Saline</i>	<i>20mg/30mg/ml</i>	<i>10ml</i>	1	<i>1.5ml</i>	<i>working</i>	<i>active</i>
4	<i>Testosterone</i>	<i>10mg</i>	<i>5g</i>	1	<i>3g</i>	<i>stock</i>	<i>active</i>
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Sample Form 7: Controlled Substance Use Form  
 SCHEDULE I – II:  or SCHEDULE III – V: \_\_\_\_\_

Note: This form is to be used to track the usage of all Schedule I – V controlled substance stock bottles. Select the drug schedule above.

Box 1: Registrant Information		
Registrant's Name: <i>Joe Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room 123, Atlanta, GA, 30325</i>

Box 2: Stock Bottle Information	
Name of Substance: <i>Fatal Plus</i>	Concentration/Strength: <i>390mg/ml</i>

Note: Record the total quantity of the substance to the nearest metric unit weight or the total number of units. The log balance must always match the physical balance of Controlled Substances. Any log discrepancies, or other circumstances that indicate significant loss or theft of controlled substance must be promptly reported using Form 5.

Box 3: Controlled Substance Use Log					Drug Name/Concentration/Strength: <i>Fatal Plus 390mg/ml</i>		
Date	Unique Bottle ID	Expiration Date of Unique Bottle ID	Starting Volume/Quantity	Amount Used	Balance Remaining	Printed Name of Person who Dispensed/Administered Drug	Reason for Use (optional)
<i>02/11/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>250 ml</i>	<i>10ml</i>	<i>240ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>02/15/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>240ml</i>	<i>20ml</i>	<i>220ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>02/19/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>220ml</i>	<i>10ml</i>	<i>210ml</i>	<i>Joe Smith</i>	<i>Dilution FPSA002</i>
<i>02/28/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>210ml</i>	<i>30ml</i>	<i>180ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/05/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>180ml</i>	<i>50ml</i>	<i>130ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>-----New Bottle Started (per PI/protocol change)-----</i>							
<i>03/10/23</i>	<i>FP002</i>	<i>06/30/26</i>	<i>250ml</i>	<i>40ml</i>	<i>210ml</i>	<i>JoAnn Taylor</i>	<i>Dr. Claus</i>
<i>03/11/23</i>	<i>FP002</i>	<i>06/30/26</i>	<i>210ml</i>	<i>10ml</i>	<i>200ml</i>	<i>JoAnn Taylor</i>	<i>Protocol 12345677</i>
<i>-----Return to Bottle FP001-----</i>							
<i>03/15/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>130ml</i>	<i>30ml</i>	<i>100ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/17/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>100ml</i>	<i>30ml</i>	<i>70ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/18/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>70ml</i>	<i>50ml</i>	<i>20ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>

## Sample Form 11: Controlled Substance Formulation/Dilution Use

Note: This form may only be used if the drug name, concentration, and total volume, created remains the same. A new form must be used if the concentration changes.

Box 1: Registrant Information				
Registrant's Name: <i>John Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room #4567, Atlanta, GA, 30325</i>		
Box 2: Calculating Concentrations from Stock Bottles				
(2a)	(2b)	(2c)	(2d)	(2e)
C/S Drug #1 name: <i>ketamine</i>	Concentration (C): <i>100mg/ml</i>	Volume Added (V): <i>2ml</i>	Total Volume (TV):  <i>10ml</i>	Conversion Factor (CF)* (CF=C x V/TV): <i>100mg x 2ml/10ml = 20</i>
Drug #2 Name: <i>xylazine</i>	Concentration (C): <i>100mg/ml</i>	Volume Added (V): <i>3ml</i>		Conversion Factor (CF)*: (CF=C x V/TV): <i>100mg x 3ml/10ml = 30</i>
Drug #3 Name(if applicable): <i>bacteriostatic saline</i>	Concentration (C): <i>n/a = 1</i>	Volume Added (V): <i>5ml</i>		Conversion Factor (CF)* (CF=C x V/TV): <i>1 x 5ml/10ml = 0.5</i>
Drug #4 Name(if applicable): <i>N/A</i>	Concentration (C): <i>N/A</i>	Volume Added (V): <i>N/A</i>		Conversion Factor (CF)* (CF=C x V/TV): <i>N/A</i>

Box 3: Working Bottle Information and Label	Working Bottle Unique ID*: <i>varied</i>
Drug Name (Box 2): <i>Ketamine/Xylazine/Saline</i>	Working Bottle Expiration Date*: <i>varied</i>
Concentration (Box 2): <i>20mg/30mg/0.5ml per ml</i>	Working Bottle 1st Puncture Date: <i>varied</i>
Total Volume Created : <i>10ml</i>	Date Mixed and Initials of person Mixing: <i>varied</i>
Fill in this side of Box 3. This info must be on the working bottle	This side of Box 3 varies per bottle but must be on the working bottle

Box 4: Drug Usage for Working Bottle				Drug Name and Concentration: <i>Ketamine/Xylazine/Saline 20mg/30mg/0.5ml per ml</i>			
Date	Unique Bottle ID	Unique Bottle ID Expiration Date	Starting Volume (ml)	Volume removed (ml)	Total Volume Remaining (TVR) (ml)	Initials of person dispensing/ administering	Reason for Use (optional)
<i>01/01/24</i>	<i>KXS010124</i>	<i>03/01/24</i>	<i>10ml</i>	<i>1ml</i>	<i>9ml</i>	<i>DB</i>	<i>Protocol #12456</i>
<i>01/05/24</i>	<i>KXS010124</i>	<i>03/01/24</i>	<i>9ml</i>	<i>5ml</i>	<i>4ml</i>	<i>DB</i>	<i>Protocol #12456</i>
<i>01/06/24</i>	<i>KXS010124</i>	<i>03/01/24</i>	<i>4ml</i>	<i>3ml</i>	<i>1ml</i>	<i>JS</i>	<i>Protocol #12456</i>
-----New Bottle created-----							

### Sample Form 4: Schedule III-V Controlled Substance Destruction Log

Box 1: Registrant Information		
Registrant's Name: <i>John Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room 123, Atlanta, GA, 30325</i>

Box 2: Reverse Distributor DEA Registrant Information		
Registrant's Name: <i>Reverse Distribution LLC</i>	DEA #: <i>DR4758590</i>	Registered Address: <i>45738 Destruction Way, Atlanta, GA, 30325</i>

Box 3: Schedule III-V Destruction Log					
Date of Destruction	Name of Controlled Substance	Concentration/Strength	Total Volume/Quantity to be destroyed	Drug Form	Unique Bottle ID
<i>02/11/23</i>	<i>Buprenorphine HCL</i>	<i>0.3mg/ml</i>	<i>1ml</i>	<i>liquid</i>	<i>BUP0010</i>
<i>02/11/23</i>	<i>Ketamine HCL</i>	<i>100mg/ml</i>	<i>2ml</i>	<i>liquid</i>	<i>KET0003</i>
<i>02/11/23</i>	<i>Testosterone Cypionate USP</i>	<i>100</i>	<i>1 grams</i>	<i>powder</i>	<i>TEST001</i>
<i>02/11/23</i>	<i>Euthasol</i>	<i>390mg</i>	<i>5ml</i>	<i>liquid</i>	<i>EUTH005</i>
<i>02/11/23</i>	<i>Lorazepam</i>	<i>1mg</i>	<i>3m</i>	<i>tablets</i>	<i>LOR0009</i>
<i>02/11/23</i>	<i>Ketamine HCL</i>	<i>100mg/ml</i>	<i>5ml</i>	<i>liquid</i>	<i>KET0004</i>
<i>02/11/23</i>	<i>Buprenorphine HCL</i>	<i>0.3mg/ml</i>	<i>0.5ml</i>	<i>liquid</i>	<i>BUP0011</i>
<i>02/11/23</i>	<i>Ketamine HCL</i>	<i>100mg/ml</i>	<i>0.5ml</i>	<i>liquid</i>	<i>KET0005</i>
<i>02/11/23</i>	<i>Buprenorphine HCL</i>	<i>0.3mg/ml</i>	<i>2ml</i>	<i>liquid</i>	<i>BUP0012</i>
<i>02/11/23</i>	<i>Euthasol</i>	<i>390mg</i>	<i>3ml</i>	<i>liquid</i>	<i>EUTH006</i>



# Questions?



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