

Appendix A. Formatting and Submission Requirements

**Specifications for the Conduct of Chemistry Activities for Toxicology
Research Performed by the
Division of Translational Toxicology at the
National Institute of Environmental Health Sciences**

A.1. Report Formatting Requirements

A.1.1. Monthly Progress Report – Content and Format

The following sections depict the required cover page format, monthly progress report content requirements for each section, and formatting requirements for the data presented.

Appendix A. Formatting and Submission Requirements (DTT Chemistry Specifications)

Contractor's Contract Number

mmddyyyy (Report Date)

STATUS REPORT – #

mmddyyyy – mmddyyyy

Chemistry Support Services for the National Toxicology Program

Contract No. N01-ES-nnnnn

Approved By:

Appendix A. Formatting and Submission Requirements (DTT Chemistry Specifications)

Submitted To:

COR

National Institute of Environmental Health Sciences

111 Alexander Drive

P.O. Box 12233

Research Triangle Park, NC 27709-2233

Chemistry Support Services Monthly Status Report – # Report Date Page

1. INTRODUCTION

This report describes the project activities performed under the chemistry support services contract for the National Institute of Environmental Health Sciences, Contract No. N01-ES-{nnnnn} during {report period}. The status of current assignments in progress during the reporting period is shown in the tables that follow. The status categories used in the tables in this report are defined as follows:

Started	Work initiated during the reporting period but not completed
Continued	Work initiated during a previous reporting period but not completed
Report	Work in either of the first two categories for which the lab work is completed and the report is in progress
Review	Work for which a report has been issued, but not yet approved
Completed	Work for which a report has been issued and approved

Table 1.1. Program and Funding Codes

Program/Funding Code	Description
<i>Funding Codes</i>	
DTT	Work done in support of DTT contract or in-house research
etc.	
<i>Program Codes</i>	
NTEC	Work done as part of the DTT nanotechnology initiative
etc.	

Table 1.2. Functional Activity Acronyms

Functional Activity Acronym	Functional Activity
BCM	Biochemical Measurement
CCA	Chemical Characterization
CH	Chemical Handling
etc.	

2. **REPORTS ISSUED**

{Number of reports} analytical reports and {number of interim reports} interim reports were issued during the {reporting period}.

2.1 BASE CONTRACT

A list of all reports issued under the Base Contract and Option Years is presented below.

Table 2.1. Reports Issued – Base Contract and Option Years

Functional Activity	Chemical Name	Work Description	Species/Strain	Status Code	Lab Assigned Work No.	ORBIT Assigned Project Task No.

2.2 OPTION X¹

A list of all reports issued under Option X is presented below.

Table 2.2. Reports Issued – Option X

Functional Activity	Chemical Name	Work Description	Species/Strain	Status Code	Lab Assigned Work No.	ORBIT Assigned Project Task No.

3. **MATERIALS HANDLING²**

3.1. SAMPLE RECEIPT

A list of all samples received under the Base Contract and Option X is presented below.

Table 3.1.1. Samples Received – Base Contract

Sample Type	Species/Strain	Sample Description	Sample Codes	Lab Assigned Work No.	ORBIT Assigned Project Task No.

¹This section may include multiple option tables if more than one option is exercised.

²Subsections may include multiple option tables if more than one option is exercised.

Table 3.1.2. Samples Received – Option X

Sample Type	Species/Strain	Sample Description	Sample Codes	Lab Assigned Work No.	ORBIT Assigned Project Task No.

3.2. PROCESSING

A list of all sample aliquots prepared under the Base Contract and Option X is presented below.

Table 3.2.1. Aliquots Prepared – Base Contract and Option Years

Aliquot Type	Species/Strain	Sample Description	Sample Codes	Lab Assigned Work No.	ORBIT Assigned Project Task No.

Table 3.2.2. Aliquots Prepared – Option X

Aliquot Type	Species/Strain	Sample Description	Sample Codes	Lab Assigned Work No.	ORBIT Assigned Project Task No.

3.3. SHIPMENT

A list of all shipments under the Base Contract and Option X is presented below.

Table 3.3.1. Shipments – Base Contract

Sample Type	Species/Strain	Sample Description	Sample Codes	Lab Assigned Work No.	ORBIT Assigned Project Task No.

Table 3.3.2. Shipments – Option X

Sample Type	Species/Strain	Sample Description	Sample Codes	Lab Assigned Work No.	ORBIT Assigned Project Task No.

4. SAFETY PROGRAM

This section describes all accidents and/or injuries, industrial hygiene, and training activities involving contract staff during the reporting period. Hazardous chemical disposal activities and costs are reported here.

4.1. ACCIDENTS/INJURIES

4.2. INDUSTRIAL HYGIENE

4.3. HAZARDOUS CHEMICALS/WASTE

Table 4.3.1. Surplus Chemicals Disposed

Chemical Name	Lot No.	Supplier	Amount Disposed

Table 4.3.2. Other Hazardous Waste Disposal

Description of Hazardous Waste

4.4. TRAINING

Table 4.4.1. Health and Safety Training

Month	Course Name	Course No.

4.5. INCIDENT RESPONSE

4.6. OTHER ITEMS

5. QUALITY ASSURANCE

A summary of the activities of the quality assurance unit is presented here along with a table that summarizes the work performed on individual assignments for the Base Contract and all exercised options during the reporting period.

Table 5. Quality Assurance Activities

Functional Activity	ORBIT Assigned Project Task No.	Lab Assigned Work No.	Description of QA Activity	Status Code	Staff Person Responsible for Work

6. INFORMATION MANAGEMENT

This section describes activities relating to computer facilities, software, and equipment used under the contract, including work performed on the contractor's information management system and databases. Activities include routine maintenance, software and hardware upgrades, and software development projects related to the contract.

7. STATUS SUMMARY**7.1. STATUS OF ALL ACTIVE ASSIGNMENTS**

The following table lists the status of all the work started, continued, reported, or completed during the reporting period.

Table 7. Active Assignment Status

ORBIT Assigned Project Task No.	Lab Assigned Work No.	Chemical Name	Functional Activity	Species/Strain (Vehicle)	Status Code*	Due Date	Date Completed

*Status Code

Comments for Active Status Table

- | | |
|---|--|
| 1 | Include numbered comments that illustrate, clarify, or elaborate the assignment status |
| 2 | Comment numbers shall be referenced in the status code column |
| 3 | |
| • | |
| • | |
| • | |

8. FISCAL DATA

Monthly and cumulative summaries of total expenditures, direct costs, and labor incurred on the project for {reporting period} are shown in the graphs. Sections 8.1 and 8.2 provide the monthly totals and cumulative contract costs for a rolling calendar year for the base effort and contract options. Costs are broken out for direct costs (attributable to a specific assignment) and administrative costs. Section 8.3 reports active assignment costs for all the work started, continued, reported, or completed during the reporting period sorted by funding source and program. Table 8.5 lists the estimated total cost, actual monthly cost, and cumulative cost for each active assignment.

Total project expenditures for {reporting period} were \$ nnn,nnn (including fee), of which \$ nnn,nnn was charged to specific assignments.

8.1. BASE CONTRACT**Table 8.1. Contract Costs – Base**

Budgeted Amount for {yyyy}: \$

Month	Monthly Direct Costs	Monthly Administrative Costs	Monthly Total Costs	Cumulative Administrative Costs	Cumulative Total Costs
January					
February					

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Month	Monthly Direct Costs	Monthly Administrative Costs	Monthly Total Costs	Cumulative Administrative Costs	Cumulative Total Costs
(etc.)					

Total Costs for {reporting period}: \$ {nnn,nnn}

8.2. OPTION(S) X (– Y)³

Table 8.2.1. Contract Costs – Option X

Budgeted Amount for yyyy: \$

Month	Monthly Direct Costs	Monthly Administrative Costs	Monthly Total Costs	Cumulative Administrative Costs	Cumulative Total Costs
January					
February					
(etc.)					

Total Costs for {reporting period}: \$ {nnn,nnn}

8.3. ACTIVE ASSIGNMENT COSTS

The following table lists all the work started, continued, reported, or completed during the reporting period for the base and each exercised option. The table is split into subtables by funding source and then by program. Total costs for each program are given after each subtable; total costs for each funding source may be found after the last subtable in each funding section.

Table 8.3.1. Active Assignment Costs

ORBIT Project Task No.	Lab Assigned Work No.	Chemical Name	CASRN	Functional Activity	Estimated Cost	Period Cost	Cumulative Cost
CHEM10207							
(etc.)							

Total Costs for {reporting period}: \$ {nnn,nnn}

Footnotes for Table 8.3.1

¹First footnote narrative...

³This section may include multiple option tables if more than one option is exercised.

8.4. COST SUMMARY

This section presents invoiced costs for the current contract year for the Base Contract and Option Years and each exercised Option.

Table 8.4.1. Cost Summary⁴

Month	Base Costs	Option X Costs	Total Cost
January			
February			
(etc.)			
Total			
Budgeted			

Table 8.4.2. Cumulative Program Annual Cost Summary (Contract Year nn)

Month	AIDS Direct Costs	AIDS Admin Costs	AIDS Total Cost	Other Program or Funding e.g., HTS, DIR, etc.
January				
February				
(etc.)				
Total				

8.5 GRAPHS

This section contains plots of monthly and cumulative expenditures and labor hours for the Base Contract, Option X, and the total contract displayed for a rolling calendar year. Plots shall be displayed such that the monthly and cumulative graphs for each contract unit are displayed on the same page. Plots shall display actual and budgeted amounts.

9. IT SECURITY PROGRAM

This section describes all IT security and training activities involving contract staff during the reporting period.

9.1. SYSTEM SCANS

9.2. SOFTWARE UPDATES

9.3. SECURITY INCIDENTS AND RESPONSE

9.4. DATA BACKUPS

9.5. TRAINING

9.6. OTHER ITEMS

⁴This table may include multiple option columns if more than one option is exercised.

A.1.2. Report Header and Cover Page Formats

Rationale

This section describes the information that must be included in each chemistry report submitted by the contractor.

General Information

To ensure that the information is presented consistently, formats for the report headers along with the information they must contain are given for each report.

For one-page reports, the format for the entire report including the header section along with the information that must be contained in the report is given.

Conventions Used in the Examples

Words to be replaced by information from the contractor are enclosed in curly braces (e.g., {Chemical Name} means the phrase “Chemical Name” is to be replaced with the name of the chemical for which the report is being written).

Words that supply information to the reader to clarify what is meant by a term in the header are enclosed in square brackets (e.g., Storage Conditions [@Analytical Lab] is intended to convey that the storage conditions to be entered here are those under which the chemical was stored at the analytical lab).

Words enclosed in parentheses are intended to indicate that the information requested should be placed in parentheses.

Words not enclosed in any type of bracket, braces, or parentheses are to be followed by the requested information (e.g., “CAS No.” should be entered into the header as CAS No. 1234-56-7). When there is a choice of words to be used as a label, they will be separated by a forward slash.

Report Headers

Absorption, Distribution, Metabolism, and Elimination (ADME) Study Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

{Test Chemical Name}	
CAS No.	Species/Strain/Sex [male HSD rat, etc.]
DTXSID:	Dose Regimen [IV, emulphor; PO, 0.5% MC]
{LAB} Chemical ID Code	Dose Groups [by route, dose concentration]
{LAB} Task No.	Sample Storage Conditions
ORBIT Project Task ID:	Test Article Receipt Date [radiolabel]
Associated ORBIT Project Task No(s). [for attached reports, when applicable]	Initial Dosing Date
Lot No. (vendor) [test chemical]	Sample Acquisition Date(s) [by study phase]
Lot No(s). (vendor(s)) [vehicle(s)]	Lab Complete Date

Mol. Wt. {TEST CHEMICAL STRUCTURE}	Mol. Formula
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Mol. Wt. {ANALYTE STRUCTURE(S)}	Mol. Formula
------------------------------------	--------------

{Repeat as needed for each metabolite}	{Repeat as needed for each metabolite}
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Executive Summary

Biosample Analysis (BMD, BSA) and OMICS Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Lot No. (vendor, city, state) (if applicable)
{LAB} Chemical ID Code	Samples Received (if applicable)
{LAB} Task/Log No.	Sample Receipt Date (if applicable)
ORBIT Project Task ID:	Submitter (if applicable)
Program Supported	Study Lab (if applicable)
	Sample Collection or Study Date (if applicable)
Analysis Date(s)	Receipt Condition (if applicable)
Interim Results Date	Shipping Container (if applicable)
Lab Complete Date	Storage Condition [@Analytical Lab] (if applicable)
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Chemical Characterization (CCA, CIPS) Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Lot No.
{LAB} Chemical ID Code	Amount Received
{Lab} Task/Log No.	Receipt Date
ORBIT Project Task ID:	Appearance
Program Supported	Submitter
Analysis Date(s)	Study Lab
Interim Results Date	Vendor (city, state)
Lab Complete Date	Vendor Purity
Draft Final Report Issued Date	Storage Conditions [@Analytical Lab]

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Chemical Characterization (MIPS) Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

ChemList ID (CLID)	Lot No. (see Table)
{LAB} Chemical ID Code	Amount Received (see Table)
{Lab} Task/Log No.	Receipt Date
ORBIT Project Task ID:	Appearance
Program Supported	Submitter
Analysis Date(s)	Study Lab
Interim Results Date	Vendor (city, state) (see Table)
Lab Complete Date	Vendor Purity (see Table)
Draft Final Report Issued Date	Storage Conditions [@Analytical Lab]

Mol. Wt. {STRUCTURE}	Mol. Formula
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Executive Summary

Table

SMILES Code	Chemical Name	CASRN	DTXSID	Supplier	Supplier City, State	Lot Number	COA Purity (%)	Determined Purity (%)	Purity System	Storage Conditions

Chemical Handling (CH) Report

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	Chemical Lot No. (vendor, city, state, vendor purity)
DTXSID:	Appearance
{LAB} Chemical ID Code	
{LAB} Task/Log No.	
ORBIT Project Task ID:	Vehicle(s)
Program Supported	Lot No(s). (vendor, city, state, purity [if applicable])
Handling Date(s)	
Lab Complete Date(s)	
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Chemical Procurement (CP) Report (One Page)

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Amount Received
{LAB} Log No.	{LAB} Receipt Date
ORBIT Project Task ID:	Lot No. (vendor, city, state)
Program Supported	Vendor Purity [% or see attached]
Appearance	Storage Conditions
Lab Complete Date	

Prepared by:

[Signature]

{Preparer}

{Title}

Approved by:

[Signature]

{Name}

Principal Investigator

Submitted To:

{COR}

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Chemical Reanalysis (CRA) Report

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Lot No. (vendor, city, state)
{LAB} Chemical ID Code	Purity ({vendor or reference to last analyzed purity})
{LAB} Task/Log No.	Samples Received
ORBIT Project Task ID:	Sample Receipt Date
Program Supported	Submitter
Nominal Dose Concentration(s)	Study Lab
Vehicle	Receipt Condition
Vehicle Lot No. (vendor)	Formulation Appearance [clear blue solution]
Mix Date(s)	Shipping Container
Analysis Date(s)	Storage Conditions [@Analytical Lab, formulation]
Interim Results Date(s)	SOP [reference to analytical SOP]
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Chemical Storage (CS) Report (One Page)

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Amount Received
{LAB} Log No.	{LAB} Receipt Date
ORBIT Project Task ID:	Received From
Program Supported	Lot No. (vendor, city, state)
	Vendor or Last Analyzed Purity [date]
Appearance	Storage Conditions

{Description of work performed}

Prepared by:

[Signature]

{Preparer}

{Title}

Approved by:

[Signature]

{Name}

Principal Investigator

Submitted To:

{COR}

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Formulation Analysis (FA, FPAS) Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Lot No. (vendor, city, state)
{LAB} Chemical ID Code	Purity ({vendor or reference to last analyzed purity})
{LAB} Task/Log No.	Samples Received {sample type, e.g., post-dosing, animal room, etc.}
ORBIT Project Task ID:	Sample Receipt Date
Program Supported	Sample Ship Date [FPAS only]
Nominal Dose Concentration(s)	Submitter
Vehicle	Study Lab
Vehicle Lot No. (vendor)	Receipt Condition
Mix Date(s)	Formulation Appearance [clear blue solution]
Analysis Date(s) [FA, FPA, and FPAS]	Shipping Container
Interim Results Date(s) [FA, FPA, and FPAS]	Storage Conditions [@Analytical Lab, formulation]
Lab Complete Date	SOP [reference to analytical SOP or DFD if not routine]
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Formulation Development (FD) Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Lot No. (vendor, city, state, vendor purity)
{LAB} Chemical ID Code	Appearance [bulk chemical]
{LAB} Task/Log No.	Storage Conditions [@Analytical Lab, bulk]
ORBIT Project Task ID:	Vehicle
Program Supported	Vehicle Lot No. (vendor, city state)
Nominal Formulation Concentrations	Storage Conditions [@Analytical Lab, vehicle]
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Multiple Chemical Handling (MCH) Report

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

ChemList ID (CLID)	
{LAB} Chemical ID Code	Appearance
{LAB} Task/Log No.	
ORBIT Project Task ID:	Vehicle(s)
Program Supported	Chemical Lot Nos. (see Table)
Handling Date(s)	
Lab Complete Date(s)	
Draft Final Report Issued Date	

*Include Chemical Lot Number (vendor, city, state, vendor purity), CASRN, DTXSID for each chemical in table

Executive Summary

Table

Code ¹	SMILES Code	Chemical Name	CASRN	DTXSID	Supplier	Supplier City, State	Lot Number	COA Purity (%)	Determined Purity ² (%)	Storage Conditions

¹If needed.

²If available.

Multiple Chemical Procurement (MCP) Report

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

ChemList ID {CLID}	
DTXSID: see Table	Amount Received: see Table
{LAB} Log No.	{LAB} Receipt Date
ORBIT Project Task ID:	Lot No. (vendor, city, state) see Table
Program Supported	Vendor Purity [% or see attached]
Appearance	Storage Conditions
Lab Complete Date	Chemical list ID

Executive Summary

{Narrative} if needed

Table

SMILE S Code	Chemical Name	CASRN	DTXSID	Supplier	Supplier City, State	Lot Number	COA Purity (%)	Amount Rec'd (g) ¹	Receipt Condition ²	Storage Conditions

¹Units should be the same for all chemicals on the list, but may differ from grams.

²Use codes – define codes in table footnotes.

Preliminary Formulation Studies (PFS) Report

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Chemical Lot No. (vendor, city, state, vendor purity)
{LAB} Chemical ID Code	Appearance
{LAB} Task/Log No.	
ORBIT Project Task ID:	Vehicle(s)
Program Supported	Lot No(s). (vendor, city, state, purity [if applicable])
Analysis Date(s)	
Interim Results Issued Date(s)	
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Protocols Development (PD) Report

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Physical Properties:
{LAB} Chemical ID Code	Appearance
{LAB} Task/Log No.	Melting Point [if applicable]
ORBIT Project Task ID:	Boiling Point [if applicable]
Program Supported	Vapor Pressure [if applicable]
	Storage Conditions [@Analytical Lab]
Lab Complete Date	
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Shipping (SHIP) Report (One Page)

One-page report. Note: font size reduced to allow display of multiple headers.

{LABNAME}

Chemistry Support Services for DTT

NIH Contract No. N01-ES-{xxxxx}

{LAB} Project {nnn-nnnn-nnn}

SHIPMENT REPORT

{CHEMICAL NAME} For multiple chemicals use ChemList name

{LAB ID NO.}

{REPORT DATE}

For bulk chemicals, use this:

CAS No.	
DTXSID:	Chemical Lot No. (vendor, city, state)
{LAB} Task/Log No.	Purity (date [if applicable]) [vendor or last analyzed purity]
ORBIT Project Task ID:	Appearance
Program Supported	Shipped To: [name and address]
Recommended Storage Conditions	Amount Shipped
Lab Complete Date	Shipping Date

Chemical Structure	Mol. Wt.	Mol. Formula

For multiple chemicals, use this:

Note: Multipage depending on Table length

DTT CAS No. [for ORBIT Project Task]	
ChemList ID (CLID):	Container Format: [microplate ID No.] or [xx-mL amber glass vial]
ORBIT Project Task ID:	Description: [e.g., 500 μ L, of 20 mM solutions in DMSO]
{LAB} Assignment No.	Supplier Lot No.: (see Table X)
Program Supported	COA Purity: (see Table X)
Recommended Storage Conditions	MIPS Purity: (see Table X) [if available]
Ship Date	Shipped To: {name and address}
Lab Complete Date	Amount Shipped: (see Table X)

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Table

Code	DTT-CID¹	Chemical Name	CASRN	DTXSID	Supplier	Supplier City, State	Lot Number	COA Purity (%)	Determined Purity² (%)	Amount Shipped (g)³

¹Used for HTS shipments (when not needed, replace with SMILES Code)

²If available

³Units may differ from grams but must be the same for all chemicals on the list.

Prepared by:

[Signature]

{Preparer}

{Title}

Approved by:

[Signature]

{Name}

Principal Investigator

Submitted To:

{COR}

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For dose vehicles, use this:

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Vehicle Lot No. (vendor)
{LAB} Log No.	{Result of Last Analysis} ({date})
ORBIT Project Task ID:	Shipped To: [name and address]
Program Supported	Amount Shipped
Recommended Storage Conditions	Shipping Date
Lab Complete Date	

For dose formulation samples, use this:

Test Chemical	
CAS No.	Amount Shipped
DTXSID:	Shipping Date
LAB Log No.	Chemical Lot No. (vendor, city, state)
ORBIT Project Task ID:	Vehicle Lot No. (vendor, city, state)
Program Supported	Sample Type
Shipped To: [name and address]	Dose concentrations including sample identification color codes.
Lab Complete Date	

Chemical Structure	Mol. Wt.	Mol. Formula

Prepared by:

Approved by:

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[Signature]

[Signature]

{Preparer}

{Name}

{Title}

Principal Investigator

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Appendix A. Formatting and Submission Requirements (DTT Chemistry Specifications)

For biological samples, use this:

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

Test Chemical	
CAS No.	Lot No. (vendor, city, state) [test chemical]
DTXSID:	Shipped To: [name and address]
{LAB} Chemical ID Code	Amount Shipped
{LAB} Task No.	Shipping Date
ORBIT Project Task ID:	Matrix Type [rat plasma, liver, etc.]
Program Supported	Dose groups (by route/vehicle) including sample identification color codes
Recommended Storage Conditions [on receipt]	Sample Acquisition Date
Lab Complete Date	Sample Storage Conditions [prior to shipment]

Chemical Structure	Mol. Wt.	Mol. Formula

Prepared by:

Approved by:

[Signature]

[Signature]

{Preparer}

{Name}

{Title}

Principal Investigator

Submitted To:

{COR}

National Institute of Environmental Health Sciences

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Special Chemical Analysis (SCA) Report

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	<i>{Contents determined by assignment type}</i>
DTXSID:	<i>{Contents determined by assignment type}</i>
{LAB} Chemical ID Code	<i>{Contents determined by assignment type}</i>
{Lab} Task/Log No.	<i>{Contents determined by assignment type}</i>
ORBIT Project Task ID	<i>{Contents determined by assignment type}</i>
Program Supported	<i>{Contents determined by assignment type}</i>
Analysis Date(s)	<i>{Contents determined by assignment type}</i>
Interim Results Date	<i>{Contents determined by assignment type}</i>
Lab Complete Date	<i>{Contents determined by assignment type}</i>
Draft Final Report Issued Date	<i>{Contents determined by assignment type}</i>

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

Toxicokinetics Study (TKS) Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

{Test Chemical Name}	
CAS No.	Species/Strain/Sex [male HSD rat, etc.]
DTXSID:	Dose Regimen [IV, emulphor; PO, 0.5% MC]
{LAB} Chemical ID Code	Dose Groups [by route, dose concentration]
{LAB} Task No.	Sample Matrices Collected [plasma, liver, urine, etc.]
ORBIT Project Task ID:	Sample Storage Conditions
Associated ORBIT Project Task No(s). [for attached reports, when applicable]	Initial Dosing Date
Lot No. (vendor, city, state) [test chemical]	Sample Acquisition Date(s) [by study phase or tissue type]
Lot No(s). (vendor(s)) [vehicle(s)]	Lab Complete Date

Mol. Wt. {TEST CHEMICAL STRUCTURE}	Mol. Formula
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Mol. Wt. {ANALYTE STRUCTURE(S)}	Mol. Formula
------------------------------------	--------------

Appendix A. Formatting and Submission Requirements (DTT Chemistry Specifications)

{Repeat as needed for each metabolite}

{Repeat as needed for each metabolite}

Executive Summary

Vehicle Analysis (VA) Reports

Contract number:

Project DTTID:

Study DTTID:

Task ID:

CASRN:

Task Name

Study Name

CAS No.	
DTXSID:	Vendor (city, state)
{LAB} Log No. [if applicable]	Lot No. [vehicle]
{LAB} Task No.	Method [reference SOP or see attached]
ORBIT Project Task ID:	Subcontractor [if applicable]
Program Supported	Samples Received
Study Supported [name or DTT study number]	Sample Receipt Date
Analysis Date(s)	Submitter [source of vehicle sample to be analyzed]
Interim Results Date(s)	Study Lab
Results [this analysis only]	Receipt Condition
Lab Complete Date	Appearance
Draft Final Report Issued Date	

Mol. Wt.	Mol. Formula
{STRUCTURE}	

Executive Summary

A.2. Data Submission Requirements

A.2.1. General Requirements

Submitted data shall be tabulated.

Tables shall include a header that describes the study from which the samples used to generate the data were obtained. Information that must be present in the header includes, but is not limited to:

Animal data: Species, strain, sex, and age of the sample source animals

Study data: Study lab, study identifier (when available), ORBIT Project DTTID

Chemical data: Chemical name, CAS reference number, DTXSID

Sample data: Matrix (or vehicle); type(s) of samples for which results are being reported (e.g., plasma, amniotic fluid, etc.; number of samples of each type received; receipt date; and analysis date(s))

Time-course data shall include a list of animal numbers and the associated species/strain/sex of the animal as well as the time point at which the sample was collected.

A summary of the method used to generate the data shall be included in the same file as the data.

The interim data file shall be uploaded to the DTT project management system and attached to the assignment that generated the data.

A.2.2. Interim Data Requirements

Interim data may be submitted in Microsoft Word™ or Excel™ formats or as a portable document format (PDF) file, depending on the data type. Except as described below, the file format shall be selected to best present the data.

Biosample method validation and analysis results; and formulation validation and time-course data shall be submitted in Excel format.

Dose analysis results shall be submitted in Word format.

Chemical characterization data may be submitted in Word or PDF format.

Compliance with Section 508 of the Rehabilitation Act of 1973 is not required for interim data submissions.

Interim data shall undergo a quality control check prior to submission but does not require quality assurance (QA) review.

A.2.3. Final Data Requirements

When a final data submission is required (Chapter 7. Reporting Requirements) for a selected assignment type, all data shall undergo QA review prior to submission.

Final data may be submitted in Microsoft Word or Excel formats or as a PDF file, depending on the data type. Except as described below, the file format shall be selected to best present the data.

Appendix A. Formatting and Submission Requirements (DTT Chemistry Specifications)

Biosample analysis results and time-course data shall be submitted in Excel format.

Dose analysis results shall be submitted in Word format.

Chemical characterization data may be submitted in Word or PDF format.

Final data submissions must be compliant with Section 508 of the Rehabilitation Act of 1973.

A.2.4. Excel File Format

Tab 1 shall include all of the header information described above.

Excel spreadsheets for time-course data shall also include the animal number information described above.

Tab 2 shall include the method summary.

Tab 3 and subsequent tabs shall include results for each species, strain, and sex for which samples were analyzed.

Data shall be organized so that data for only one species/strain/sex and dose are presented on each tab.

Each tab shall contain header information with the study, species/strain/sex data presented on the tab, sample receipt dates, analysis dates, ORBIT Project Task number, and lab standard operating procedure (SOP) or analytical method number used for the analysis.

Tabs shall be labeled with the species-sex and dose of the sample results presented on the tab, e.g., M-mouse 500 mg/kg.