

CCP-QP-006

Revision 9

CCP Corrective Action Reporting and Control

EFFECTIVE DATE: 09/26/2007

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PRINTED NAME

APPROVED FOR USE

RECORD OF REVISION

Revision Number	Date Approved	Description of Revision
4	02/13/2003	Total re-write to address issues identified in CAR-CCP-0512-02, revision 0, First Quarter 2002, Trend Report (ref; Inter-Office Correspondence TP:02:04131), WTS Audit 1 02-07 and to comply with format requirements of CCP-QP-010. Due to the major revision, no redlines are used. Resolved CBFO comments.
5	08/28/2003	Separated electronically fillable forms and updated references in procedure.
6	03/10/05	Procedure being changed to align with CCP-QP-004 and the new CCP-QP-014, Data Analysis and Trending.
7	04/04/2005	Editorial changes and changing of Note which contradicted itself.
8	11/16/2006	Revised to implement the Waste Isolation Pilot Plant Hazardous Waste Facility Permit requirements resulting from the Section 311/Remote-Handled (RH) Permit Modification Request (PMR). In addition, includes some records process, editorial, and format improvements.
9	09/26/2007	Revised to incorporate the Central Characterization Project (CCP) Quality Assurance (QA) Manager's documentation of decisions, editorial, and format improvements.

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1.0 PURPOSE

This procedure, used in conjunction with CCP-QP-004, *CCP Corrective Action Management*, identifies the process for documenting, evaluating, and controlling conditions adverse to quality through the use of Corrective Action Reports (CARs).

1.1 Scope

This procedure applies to activities affecting the quality of Central Characterization Project (CCP) waste characterization, certification, packaging, and transportation. It establishes the process for identifying, documenting, controlling, evaluating, dispositioning, and verifying completion of corrective actions for conditions adverse to quality related to programmatic or process failures, malfunctions, and deficiencies.

Reporting and control of hardware and batch data report (BDR) deficiencies is covered in CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control*.

Evaluations for significant and recurring conditions adverse to quality are addressed in CCP-QP-004.

Evaluation of CARs for Price-Anderson Amendment Act (PAAA) issues and activities are covered in CCP-PO-008, *CCP Quality Assurance Interface with the WTS Quality Assurance Program*.

Trending of conditions adverse to quality is addressed in CCP-QP-014, *CCP Quality Assurance Trend Analysis and Reporting*.

2.0 REQUIREMENTS

2.1 References

Baseline Documents

- DOE/CBFO-94-1012, U.S. Department of Energy, Carlsbad Field Office (CBFO), *Quality Assurance Program Document (QAPD)*
- DOE/WIPP-02-3214, *Remote-Handled TRU Waste Characterization Program Implementation Plan*
- CCP-PO-001, *CCP Transuranic Waste Characterization Quality Assurance Project Plan*
- CCP-PO-002, *CCP Transuranic Waste Certification Plan*

Referenced Documents

- CCP-PO-008, *CCP Quality Assurance Interface with the WTS Quality Assurance Program*
- CCP-QP-004, *CCP Corrective Action Management*
- CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control*
- CCP-QP-008, *CCP Records Management*
- CCP-QP-014, *Quality Assurance Trend Analysis and Reporting*

2.2 Conditions Adverse to Quality

2.2.1 CCP personnel who discover conditions adverse to quality are responsible for either originating a CAR and/or notifying the manager of the adverse condition. Managers are responsible for originating a CAR when notified by personnel of conditions adverse to quality.

2.2.2 CCP Personnel evaluating and determining the disposition for adverse conditions will have demonstrated competence in the specific area they are evaluating, adequate understanding of the requirements, and access to pertinent background information.

2.3 Reporting and Control

2.3.1 Conditions adverse to quality will be documented on Attachment 1, Corrective Action Report, by the individual identifying the problem or the manager of the adverse condition in accordance with the requirements of this procedure. Responsible manager will be notified and corrective actions taken, documented, and verified.

2.3.2 CARs will clearly identify and describe the required condition (i.e., procedure, section, paragraph, including revision), and the characteristics that do **NOT** conform to specified requirements.

2.3.3 CARs will have a unique numbering and logging system. The logging system will account for all CARs issued, including voided CARs. Attachment 3, CCP CAR Log, will, at a minimum, identify the following:

- CAR Number
- Brief Description of CAR Condition
- Initiation Date
- Significant (Y/N), if known
- Responsible Manager

2.3.4 The CAR numbering system (e.g., CAR-LANL-0001-05, Rev. 0; CAR-SRS-0001-05, Rev. 1; CAR-CCP-0001-05, Rev. 2) will provide the capability to determine the following:

- CAR
- Site designator
- Sequential number issued for the organization or site in that calendar year
- Calendar year issued
- Revision Number

2.4 CAR Evaluation, Disposition, and Closure

2.4.1 CCP Quality Assurance (QA) will concur with the CAR before the evaluation and disposition process.

2.4.2 CCP QA will evaluate the CAR for significant and recurring conditions adverse to quality in accordance with CCP-QP-004.

2.5 Corrective Action Plans (CAPs)

2.5.1 CAPs and evaluations will be accomplished in accordance with this procedure in conjunction with CCP-QP-004.

2.6 Corrective Action Report Module (CARM)

2.6.1 The CARM will provide the capability for an accurate and timely reporting of the status of all CARs.

2.6.2 The CARM will provide the information necessary to support trending of conditions adverse to quality.

2.6.3 The CARM will provide, as a minimum, the following:

- CAR Number and Revision
- CAR Initiation Date
- CAR Initiator
- Requirement Condition
- Actual Condition
- Expected Completion Date
- Responsible Manager
- Trend Code
- Significant Condition Adverse to Quality (SCAQ) or Condition Adverse to Quality
- Closure Date, if applicable

3.0 RESPONSIBILITIES

3.1 CAR Originator

- 3.1.1 Identifies the condition adverse to quality and initiates the corrective action process in accordance with the requirements of this procedure.

3.2 CCP Quality Assurance (QA)

NOTE

The responsibilities listed in Section 3.2 are assigned to designated CCP QA personnel.

- 3.2.1 Ensures the CAR process is followed in accordance with this procedure.

- 3.2.2 Validates CARs.

- 3.2.3 Determines the appropriate trend code, in accordance with CCP-QP-014.

- 3.2.4 Performs CAR evaluations in accordance with this procedure and CCP-QP-004.

- 3.2.5 Participates in the preparation of Deficiency Evaluation Forms (DEF) in accordance with CCP-QP-004.

- 3.2.6 Approves corrective actions.

- 3.2.7 Verifies corrective action is complete and adequate.

- 3.2.8 Closes CARs.

3.3 CCP Quality Assurance (QA) Manager

- 3.3.1 Confirms the CAR has been correctly evaluated and completed in accordance with this procedure and CCP-QP-004.

- 3.3.2 Ensures personnel performing CAR evaluations and dispositions have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

- 3.3.3 Approves CARs.

| 3.4 Responsible Manager

3.4.1 Identifies necessary corrective actions to resolve conditions adverse to quality and precludes recurrence in accordance with this procedure.

3.4.2 Monitors to ensure corrective actions are completed in accordance with the established dates.

3.4.3 Provides objective evidence of completion of corrective actions.

3.5 CCP Site Project Manager (SPM)

3.5.1 Determines if CBFO notification is required for significant CARs.

3.6 CAR Coordinator

3.6.1 Maintains the CAR Log.

3.6.2 Updates CARM.

3.6.3 Processes CARs in accordance with this procedure.

3.6.4 Maintains CARs in accordance with CCP-QP-008.

3.6.5 Reconciles CAR Logs in accordance with this procedure.

| 3.7 Initiator

| 3.7.1 Responsible for starting the revision process when necessary.

4.0 PROCEDURE

4.1 CAR Initiation

CAR Originator

4.1.1 Upon identification of a condition adverse to quality, perform the following:

- [A] Obtain a CAR number from the CAR Coordinator.
- [B] Enter the number and revision on both pages of Attachment 1.
- [C] Complete Blocks 1 thru 3b of Attachment 1.
- [D] Confirm that Block 3b of Attachment 1 addresses the applicable section(s) and the revision of the implementing procedure and/or requirement.
- [E] Print name, sign, and date Block 5 of Attachment 1.

4.1.2 Forward the CAR to CCP QA, **OR** perform the next step, if qualified.

4.2 CAR Review and Validation

CCP QA

4.2.1 Review and validate the CAR by performing the following as a minimum:

- [A] Verify that the identified condition and requirement meet the criteria for a CAR (i.e., programmatic or process failures, malfunctions, and deficiencies), and **NOT** exclusively the criteria for hardware items which are addressed in CCP-QP-005.

NOTE

The identified deficiencies may require both a CAR and a Nonconformance Report (NCR): A CAR to address programmatic issues, and an NCR to provide control of nonconforming items to prevent inadvertent use.

- [B] **IF** the identified condition is determined to meet the criteria for an NCR, but **NOT** a CAR, **THEN** void the CAR in accordance with step 4.10, **AND** instruct the initiator to initiate an NCR in accordance with CCP-QP-005.

- [C] **IF** it is determined to be a valid CAR,
THEN verify the following:
- CAR number and revision are on both pages of the CAR
 - Form is filled out correctly
- [D] Verify that the condition requiring corrective action adequately addresses the identified requirement (procedure, section, and revision).
- [E] Determine whether the condition is a SCAQ in accordance with CCP-QP-004, **AND** check the appropriate box in Block 4a of Attachment 1.
- [F] Determine if a CAP is required, **AND** check the appropriate box in Block 4b of Attachment 1.
- [G] Determine the Trend Code in accordance with CCP-QP-014, **AND** indicate the code in Block 4c of Attachment 1.
-

NOTE

If any inconsistencies, clarifications, or other concerns are identified, they shall be resolved with the CAR Originator, then reprocessed in accordance with Section 4.2.

- 4.2.2 **IF** the CAR is determined to be valid,
THEN validate the CAR by printing name, signing, and dating Block 6 of Attachment 1
AND GO TO step 4.2.4.
- 4.2.3 **IF** the CAR is determined to be invalid,
THEN void the CAR in accordance with step 4.10.
-

NOTE

The responsible manager determination is based on negotiations and agreement between CCP QA and CCP management, with CCP QA making the final determination.

- 4.2.4 Determine the manager responsible for resolution, (i.e., the Responsible Manager).
- 4.2.5 Enter the Responsible Manager's name in Block 7 of Attachment 1.

4.2.6 Discuss the following with the Responsible Manager:

- Conditions identified in the CAR
- Recommendations for corrective actions
- Initial response due date

4.2.7 Record the Initial Response Due Date in Block 10 of Attachment 1.

4.2.8 Forward the CAR to the CCP Project Office for approval by the CCP QA Manager.

4.3 CAR Review and Approval

CCP QA Manager

4.3.1 Review the CAR to validate the adverse condition and applicable requirement.

4.3.2 Confirm that the adverse condition has been correctly evaluated **AND** documented in Block 4a. Provide additional documentation in accordance with CCP-QP-004, as necessary.

4.3.3 Review the DEF, if applicable, or the CAP, if applicable, to assure all the requirements of CCP-QP-004 have been adequately addressed.

4.3.4 **IF** the CAR can **NOT** be validated,
THEN return the CAR to CCP QA for resolution.

4.3.5 **WHEN** the CAR can be validated,
THEN print name, sign, and date Block 8 of Attachment 1, **AND** forward the original CAR to the CAR Coordinator for processing.

4.4 CAR Processing

CAR Coordinator

NOTE

This section is performed at the point where the CAR Coordinator receives the CAR from the CCP QA Manager.

4.4.1 Verify CAR information in the CAR Log.

4.4.2 Update CARM.

NOTE

Additional distribution requirements, in addition to the Standard Distribution, should be provided by the CCP QA Manager, if applicable, to the CAR Coordinator.

4.4.3 Coordinate the preparation of a cover letter signed by the CCP QA Manager to transmit a copy of the approved CAR to the Responsible Manager, **AND** ensure distribution to the CCP SPM, PAAA Coordinator, CAR originator, and any others, as identified by the CCP QA Manager.

4.4.4 Retain original CAR, **AND** attach a copy of the CAR to the cover letter.

4.4.5 Transmit cover letter with the attached copy of the CAR to Responsible Manager, **AND** distribute copies to those entities identified for distribution in step 4.4.3.

4.5 Corrective Action Determination

Responsible Manager

4.5.1 **IF** a CAP is required,
THEN prepare the CAP in accordance with CCP-QP-004, **AND** enter "See attached Corrective Action Plan" in Block 9 of Attachment 1.

4.5.2 **IF** a CAP is **NOT** required,
THEN investigate, **AND** document all corrective actions necessary to resolve the deficiency in Block 9 of Attachment 1, using Attachment 2, CCP CAR Continuation Sheet, if necessary.

4.5.3 Verify that the corrective action addresses, as a minimum, the following:

- Cause
- Impact of the deficiency on completed work
- Detailed corrective actions to correct the deficiency
- Identification of documentation needed to substantiate completion of corrective actions

- 4.5.4 Consider the need to address the following, **AND**, if deemed necessary, document in Block 9 of Attachment 1:
- Immediate/Compensatory actions
 - Extent of condition
 - Actions taken to preclude recurrence of the problem
- 4.5.5 **IF** the CAR is significant and Sections 6 and 7 of the DEF have been completed in accordance with CCP-QP-004, **THEN GO TO** step 4.5.7.
- 4.5.6 **IF** the CAR is significant, and Sections 6 and 7 of the DEF have **NOT** been completed in accordance with CCP-QP-004, **THEN** complete those items, **AND** document them in Block 9 of Attachment 1.
- 4.5.7 Enter expected Completion Date in Block 10 of Attachment 1.
- 4.5.8 Print, sign, and date Block 12 of Attachment 1, **AND** forward original CAR and attachments, if applicable, to CCP QA.

NOTE

Corrective Actions for CARs initiated at the CCP Project Office **MUST** be approved by the CCP Project Office.

4.6 Corrective Action Approval

CCP QA

- 4.6.1 Review the CAR and applicable attachments, **AND** determine the following:
- [A] The corrective actions in Block 9 of Attachment 1 or, if applicable, CAP adequately addresses measures to be taken to correct the identified deficiency and preclude recurrence.
 - [B] Assure corrective actions address all items on the DEF in accordance with CCP-QP-004, if applicable.
 - [C] Assure that an expected completion date is identified in Block 10 of Attachment 1.

- 4.6.2 **IF** corrective action is deemed appropriate,
THEN approve by completing Block 13 of Attachment 1 **AND**
GO TO step 4.6.4.
- 4.6.3 **IF** corrective action is deemed to be deficient,
THEN make recommendations for corrective actions; resolve with
responsible manager, **AND** reprocess per Section 4.6.
- 4.6.4 Forward CAR and attachments (if applicable) to the CAR
Coordinator for processing.

4.7 CARM Update

CAR Coordinator

NOTE

This section is performed once the CAR Coordinator receives the CAR
from CCP QA.

- 4.7.1 Update CARM.
- 4.7.2 File original CAR and any attachments as a working file until CAR
closure and maintain in accordance with CCP-QP-008.

Responsible Manager

- 4.7.3 Upon completion of the required corrective actions, request the
original CAR from the CAR Coordinator.

CAR Coordinator

- 4.7.4 Upon receiving request for the original CAR to be sent to the
Responsible Manager for closure, ensure the open CAR is scanned
and available on Duran.

- 4.7.5 Forward the original CAR to the Responsible Manager.

Responsible Manager

- 4.7.6 Receive original CAR from the CAR Coordinator.

4.7.7 Provide objective evidence of completion by one or more or any combination of the following:

- [A] Attachments prepared as required by step 4.11.
- [B] Reference to traceable documentation that substantiates completion of corrective actions and actions to preclude recurrence.
- [C] Statement(s) of Fact, name printed, signed, and dated and included as an attachment.

NOTE

Discussions with CCP QA may be conducted to review the documentation that substantiates completion of corrective actions prior to formal submittal in order to ensure that the documentation is adequate.

4.7.8 Document in Block 14 of Attachment 1, the documentation from the step above that substantiates completion of corrective actions.

4.7.9 Print name, sign and date Block 15 of Attachment 1, **AND** submit original CAR with attachments, if applicable, to CCP QA.

4.8 Completion Verification and Closure

CCP QA

4.8.1 Review original CAR **AND** verify the following:

- [A] Block 14 of Attachment 1 provides traceability to objective evidence substantiating completion of corrective action.
- [B] Documentation provides adequate objective evidence of completion of corrective actions.
- [C] CAR is completed as required by this procedure and CCP-QP-004, as applicable.
- [D] Verify Block 11 of Attachment 1 applicability, **AND**
 - [D.1] **IF** blank,
THEN check the NO block.

4.8.2 **IF** corrective action and/or other requirements of step 4.8.1 are **NOT** satisfactorily completed, **THEN** perform the following:

[A] Return the original CAR to the Responsible Manager, with detailed reasons for return, for correction, and re-submittal.

4.8.3 **IF** corrective action and/or other requirements per step 4.8.1 are satisfactorily completed, **THEN** enter the verification methods used in Block 16a of Attachment 1, **AND** print name, sign, and date in Block 16b of Attachment 1.

4.8.4 Forward closed original CAR **AND** attachments, if applicable, to the CAR Coordinator for processing.

4.9 Closeout

CAR Coordinator

NOTE

This section is performed once the CAR Coordinator receives the closed original CAR from CCP QA.

4.9.1 Update CARM.

4.9.2 Submit closed original CAR **AND** attachments, if applicable, to CCP Records Center.

4.10 Voiding CARs

CCP QA

4.10.1 **IF** a CAR is determined to be invalid during the review in accordance with Section 4.2, **THEN** perform the following:

[A] Draw a diagonal line across each page of the CAR, **AND** mark "VOID" with an initial and date.

[B] Provide detailed justification for voiding.

CCP QA/CAR Originator

[C] Print name, sign, and date adjacent to the justification concurring with the reason for voiding, **AND** forward the CAR to the CAR Coordinator.

CAR Coordinator

4.10.2 Update the CAR Log identifying that the CAR is voided.

4.10.3 Input the CAR into CARM.

4.10.4 Submit voided CAR to CCP Records Center.

Responsible Manager/ CCP QA/CCP QA Manager

4.10.5 Any time during the life cycle of the CAR, after approval, when it is determined that the CAR should be voided, perform the following:

[A] Provide a detailed justification for voiding, **AND** obtain concurrence from the CAR Originator, CCP QA, Responsible Manager, and the CCP QA Manager.

Originator/CCP QA/Responsible Manager/CCP QA Manager

[B] Sign and date adjacent to the justification concurring with the reason for voiding **AND** forward the CAR to the CAR Coordinator.

[C] Process in accordance with steps 4.10.1 through 4.10.4.

4.11 Attachments

Initiator/CCP QA/CCP QA Manager/Responsible Manager

4.11.1 When using attachments for a CAR, perform the following:

[A] Identify the CAR number and revision on each page of the attachment.

[B] Identify the attachment number.

NOTE

EXAMPLE - CAR-LANL-0003-05, Rev. 0, Attachment 1, Page 1 of 1
CAR-SRS-0004-05, Rev. 1, Attachment 2, Page 1 of 6

[C] Paginate each page of the attachment.

4.12 Extensions

Responsible Manager

4.12.1 In the event that a CAR can **NOT** be completed by the expected completion date, determine a new date **AND** initiate an e-mail or inter-office memo (IOM) to the CCP QA/CAR Coordinator (CAR Point-of-Contact) requesting an extension.

CCP QA

4.12.2 Record the new date in Block 11 of Attachment 1, mark the Yes box, **AND** attach e-mail or IOM to the CAR as required by step 4.11.

4.12.3 Forward to the CAR Coordinator.

CAR Coordinator

4.12.4 Update the CARM with the new completion date.

Responsible Manager

4.12.5 **IF** a need arises to request another extension, **THEN** perform the following:

- [A] Initiate an e-mail or IOM to the responsible manager's immediate supervisor/manager requesting approval to extend, identifying the new completion date **AND** a justification as to why extension is needed.
- [B] Obtain approval.
- [C] Submit the e-mail or IOM, approved by the responsible manager's supervisor/manager, to CCP QA/CAR Coordinator to be included with the CAR-supporting data.

CCP QA/CAR Coordinator

4.12.6 Process the e-mail or IOM in accordance with steps 4.12.2 through 4.12.4.

4.13 Revisions and Corrections

Initiator/CCP QA/CCP QA Manager/Responsible Manager

NOTE

After CCP QA Manager approval of the CAR, any changes to technical content shall require a revision which will be performed in accordance with this section.

Editorial changes, **NOT** affecting technical content may be lined through, **AND** the correct data entered, initialed and dated during the life cycle of the CAR.

4.13.1 Apply next sequential revision number to all pages of the CAR and all attachments.

4.13.2 Use vertical bars along the left hand side of all applicable pages to identify the required changes.

4.13.3 Supersede the previous revision by drawing a diagonal line across each page, adding a statement, "Superseded by Revision # (next sequential rev #)" **AND** initial and dating.

4.13.4 Attach the superseded revision to the new revision.

4.13.5 Submit the new revision for review and approval in accordance with Sections 4.2 and 4.3.

4.14 CAR Log Reconciliation

NOTE

Annually, the Master CAR Log is reconciled in accordance with this section.

CAR Coordinator

4.14.1 Reconcile the Master CAR Log to determine if the blocks of numbers issued versus the actual numbers used are accurate.

4.14.2 Annotate unused numbers during the calendar year as "Number Not Used" in the Master CAR Log.

4.14.3 Print the Master CAR Log annually after reconciliation, **AND** submit to CCP Records Center in accordance with CCP-QP-008.

5.0 RECORDS

5.1 Records generated by this procedure will be maintained as QA records in accordance with CCP-QP-008. The records are the following:

5.1.1 QA/Nonpermanent Records

- [A] Attachment 1, *Corrective Action Report* and supporting documentation, if applicable
- [B] Attachment 2, Corrective Action Report Continuation Sheet, if applicable
- [C] Attachment 3, CAR Log
- [D] CBFO Notifications
- [E] Corrective Action Plan (Generated in CCP-QP-004)
- [F] Deficiency Evaluation Form (Generated in CCP-QP-004)
- [G] CCP CARM Data Output
- [H] Management email, if applicable (Generated in CCP-QP-004)

Attachment 1 – Corrective Action Report

Page ____ of ____

CCP CORRECTIVE ACTION REPORT	
CAR No: <u>CAR -</u>	Revision No.
1. Facility/Organization	2. Supplier Name/Address (if applicable)
DESCRIPTION OF DEFICIENCY	
3a. Description of Condition Requiring Corrective Action (Use CAR Continuation Sheet, Attachment 2, if necessary)	
3b. Requirement, including revision	
4a. Significant Condition Adverse to Quality?	<input type="checkbox"/> Yes <input type="checkbox"/> No (If yes, see attached DEF)
4b. Corrective Action Plan Required?	<input type="checkbox"/> Yes <input type="checkbox"/> No (Previous CARs)
4c. Trend Code	
5. Originator (<i>Print name, sign and date.</i>)	6. CCP QA Concurrence (<i>Print name, sign and date.</i>)
7. Assigned Responsible Manager (<i>Print name</i>)	8. CCP QA Manager Approval (<i>Print name, sign and date.</i>)

Attachment 1 – Corrective Action Report (continued)

Page ____ of ____

CAR No: <u>CAR</u> -		Revision No.	
9. Cause and Action to Correct Deficiency (Use CAR Continuation Sheet, Attachment 2, if necessary)			
10. Initial Response Due Date Expected Completion Date	11. Extension Requested? Expected Completion Date	<input type="checkbox"/> Yes	<input type="checkbox"/> No
CORRECTIVE ACTION APPROVALS			
12. Responsible Manager (<i>Print name, sign and date</i>)		13. CCP QA Approval (<i>Print name, sign and date</i>)	
CLOSURE			
14. Corrective Action Completion Documentation (Attachment 2, if necessary) [To be completed after completion of corrective action(s)]			
15. Corrective Action Complete - Responsible Manager (<i>Print name, sign and date</i>)			
16a. Verification Methods:			
16b. Corrective Action Verified CCP QA Approval (<i>Print name, sign and date</i>)			

Attachment 2 – Corrective Action Report Continuation Sheet

Page ____ of ____

CCP CORRECTIVE ACTION REPORT CONTINUATION SHEET	
CAR No: <u>CAR-</u>	Revision No.
Continuation from Section Number	

