

ARCOS Reporter Training

Drug Enforcement Administration
Diversion Control Division

www.DEAdiversion.usdoj.gov

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ARCOS Unit

Phone: 202-307-8600

Email: ARCOS_Unit@usdoj.gov

Fax: 202-307-8612

Controlled Substances Act

ü 21 U.S.C. § 827: Manufacturers and Distributors are required to report Controlled Substance activity to the Attorney General

Ø Attorney General delegates to DEA

Ø DEA = ARCOS

Controlled Substances Act

ü ARCOS =

Automation of
Reports and
Consolidated
Orders
System

ARCOS Unit

- ü Understanding reporting requirements

- ü Technical issues

- ü NDC dictionary

Who Reports to ARCOS?

- ü Manufacturers
- ü Repackagers*
- ü Relabelers*
- ü Distributors
- ü Reverse Distributors

*Per 21 U.S.C. § 802(15), these activities are considered “manufacturing”

What is Reported to ARCOS?

- ü Acquisition and Distribution

- ü End-of-year Inventory

- ü C-I, C-II, C-III narcotics
and GHB materials

- ü Destruction

What is Reported to ARCOS?

- ü Manufacturing
(see Section 6 of Handbook)

- ü Also psychotropics listed in
21 C.F.R. § 1304.33(d)

What is Reported to ARCOS?

- ü No activity for reporting period
- ü No end-of-year inventory (ARCOS)
 - ü Theft and loss
 - ü Returns vs. purchases
 - ü Waste

What is Reported to ARCOS?

Repackaging and Relabeling

- ü Registered as Manufacturer
- ü Contact FDA for labeler code
- ü General Email: EDRLS@fda.hhs.gov
- ü Do not use original NDC

What is Reported to ARCOS?

End-of-Year Inventory

- ü Quarterly: Part of 4th quarter report
- ü Monthly: Part of December report
- ü Separate from YERS report (Quota)
 - ü On-hand as of COB December 31st
 - ü Transaction Code 8 – no inventory

What is Reported to ARCOS?

Manufacturing

- ü 4th quarter or December submission
- ü Cumulative for the year
- ü Section 6 of Handbook

Filing Reports

ü Due the 15th day of the month following the end of the reporting period (*21 C.F.R. § 1304.33(b)*)

ü Extensions cannot be granted by the ARCOS Unit

Filing Reports

- ü Quarterly or monthly
- ü Electronic or manual
- ü EDI upload print-out is not confirmation that the report was successfully processed
- ü Cannot file prior to end of period

Filing Reports

Methods of Reporting

- ü ARCOS Online
- ü EDI (text file) upload
 - ü DEA Form 333
- ü Obtain an online account

Filing Reports

Methods of Reporting

ARCOS Online

- Ø Initial release – eliminated PC Field Edit
 - Ø Direct entry into website; errors detected “up front”
- Ø Error correction (any reporting method)
 - Ø Account management

Filing Reports

Methods of Reporting

EDI Upload

- Ø PC Field Edit – no longer supported
- Ø Must be text file format; 80-character
 - Ø Large volume
- Ø Integration with ARCOS Online

Filing Reports

Methods of Reporting

DEA Form 333

- Ø Must be requested
- Ø Longer process – mailing, data entry
- Ø Good backup option; computer problems

Filing Reports

Central Reporting

- Ø “Single” = default reporting method, one registration
- Ø “Central” = records for multiple registrations held at one location
- Ø Field office authorization required (21 C.F.R. 1304.04)

Filing Reports

Central Reporting

- Ø Proper formatting of Control Record – Central Reporter registration must be included in appropriate field (EDI and paper reporting only)

Filing Reports

Reporting Exceptions

- ü DEA cannot grant exceptions to requirements imposed by the Controlled Substances Act under 21 U.S.C. § 827(d)
- ü Reporting of controlled substance activity as required by the Attorney General

Filing Reports

Reporting Exceptions

- ü HOWEVER ... DEA may grant an exception from ARCOS reporting provisions of 21 C.F.R. 1304.33 to the extent that they go beyond what is required by statute (per 21 C.F.R. § 1307.03)

Filing Reports

Reporting Exceptions

- ü Simply put ... Exception requests must be directed to the Assistant Administrator in charge of the Diversion Control Division
- ü Must continue reporting until or unless an exception is granted

Updating Contact Information

- ü Paper request form – ARCOS website (“ARCOS Participant Information Update Form”)
- ü Email or letter is fine
- ü ARCOS Online – “Manage Participant Data” button

Updating Contact Information

- ü Reporter's responsibility to keep contact information current
- ü POC for reporting issues – delinquencies, errors, announcements
- ü Also reporting frequency updates

ARCOS NDC Dictionary

Submitting Labels or Documentation

Ø Email to ARCOS_Unit@usdoj.gov

Ø Fax to 202-307-8612

Ø Upload via ARCOS Online reporting system – must be pdf file

ARCOS NDC Dictionary

Submitting Labels or Documentation

Ø Transactions cannot be processed unless the NDC has been added to the ARCOS dictionary

ARCOS NDC Dictionary

Non-Reportable vs. Non-Scheduled

ü Non-Reportable = Controlled

Substances not reportable to ARCOS

- Ø Can be added to ARCOS dictionary – help clear errors and future reporting
- Ø Examples include anabolic steroids and C-V Codeine preparations

ARCOS NDC Dictionary

Non-Reportable vs. Non-Scheduled

ü Non-Scheduled = Not C-I through C-V
Controlled Substance

- Ø Cannot be added to ARCOS dictionary
- Ø Will always result in an error if reported
- Ø “Controlled Substance Schedules” on
Diversion website

ARCOS NDC Dictionary

Non-Reportable vs. Non-Scheduled

ü Non-Scheduled = Not C-I through C-V
Controlled Substance

Ø Examples include over-the-counter medications and List 1 Chemicals

ARCOS NDC Dictionary

Use of "Generic" NDCs

- ü "G" number or "pseudo" provided by
ARCOS Unit
- ü Import/export documentation
 - ü Reverse Distributors
 - ü Manufacturing activities

ARCOS Transactions

- ü ARCOS Online: Fillable fields
- ü EDI (text file): 80-character string
- ü DEA Form 333: 63 boxes (characters)

ARCOS Transactions

- ∅ Control Record
- ∅ Transaction Code
- ∅ Action Indicator
- ∅ National Drug Code
- ∅ Quantity
- ∅ Unit Code
- ∅ Associate Registration
- ∅ Order Form Number
- ∅ Correction Number
- ∅ Strength
- ∅ Transaction Date
- ∅ Transaction ID

ARCOS Transactions

Control Record

- Ø “Year 2000 Formatting Changes”
- Ø EDI (text file) and paper report only
- Ø Problems with Control Record =
report not processed

ARCOS Transactions

Control Record

- Ø Reporting Frequency = "M" or "Q"
 - Ø Date must be end-of-period and 8-digit
- Ø Improper use of Central Reporter field; subsidiaries only & registered Central Reporters

ARCOS Transactions

Transaction Code

- Ø Section 5.4.3 through Section 5.8.3 of ARCOS Registrant Handbook
- Ø Section 6 of Handbook for manufacturing activities
- Ø Appendices 1 & 2: What is required for each Transaction Code

ARCOS Transactions

Transaction Code

- Ø Acquisitions and Increases
- Ø Dispositions and Decreases
 - Ø Inventory
 - Ø Manufacturing
 - Ø Miscellaneous/Other

ARCOS Transactions

Transaction Code

- Ø Trans Code "P" vs. Trans Code "R"
- Ø Trans Codes "1" and "5" – contact ARCOS Unit; do not use "F"
- Ø Trans Code "Y" – reported by registrant performing destruction

ARCOS Transactions

Transaction Code

Ø Inventory = Trans Codes "3," "4," or "8"; if not present, no credit given for ARCOS end-of-year inventory

Ø Trans Code "7" required if no activity for reporting period

ARCOS Transactions

Transaction Code

∅ Manufacturing ...

- ∨ If uncertain, email ARCOS Unit detailed information on activity
- ∨ Remember, cumulative at end of the year; permission needed for more frequent

ARCOS Transactions

Transaction Code

- Ø Exceptions to Manufacturing ...
- ✓ Quantity of a drug is used to produce a product containing the same drug in the same schedule
- ✓ Waste, samples, etc. must still be reported

ARCOS Transactions

Action Indicator

Ø EDI (text file) upload and paper form only; not ARCOS Online

Ø Used in 3 instances – Insert ("I"), Delete ("D"), or Adjust ("D" & "A")

ARCOS Transactions

Action Indicator

- ∅ Delete/Adjust Transaction Pairing –
See Section 7.8.2 of the Handbook
- ∅ Action Indicator cannot be used on
error transactions
- ∅ Action Indicator “A” cannot be used
without Action Indicator “D”

ARCOS Transactions

National Drug Code (NDC)

- Ø Remember 5 – 4 – 2 format, with zero fill in each section
 - ✓ Example: 12345-123-1 would be 12345-0123-01
 - ✓ Example: 1234-0123-01 would be 01234-0123-01

ARCOS Transactions

National Drug Code (NDC)

Ø Again ... NDC must be in ARCOS dictionary before transaction can be processed

Ø Only report materials per
21 C.F.R. § 1304.33

ARCOS Transactions

Quantity

- Ø Bulk, raw material: Used with Unit and Strength to report *weight or volume*
- Ø Bulk, finished product: Used to report *total number of tablets, capsules, etc.*
- Ø Finished product/package: Used to report *total number of packages*

ARCOS Transactions

Quantity

∅ The Quantity must be greater than zero to avoid an uncorrectable error

ARCOS Transactions

Unit (or Unit Code)

Ø If the NDC represents a bulk, raw material, the Unit must be ...

§ 1 = micrograms

§ 2 = milligrams

§ 3 = grams

§ 4 = kilograms

ARCOS Transactions

Unit (or Unit Code)

Ø If the NDC represents a bulk liquid, the Unit can be blank to report number of milliliters, or ...

§ 5 = milliliters

§ 6 = liters

ARCOS Transactions

Unit (or Unit Code)

Ø If the NDC represents a finished package, the Unit must be ...

§ Blank (most likely)

§ D = dozens (x12)

§ K = thousands (x1,000)

ARCOS Transactions

Associate Registration

- ∅ On the “other end” of the transaction, in most instances
- ∅ Can also reference local DEA office in instances such as destruction
 - ∅ Not always required – see Appendices 1 & 2 in Handbook

ARCOS Transactions

Order Form Number

- Ø Required for acquisition and distribution transactions involving C-I and C-II drugs; possible exception with unsolicited returns
- Ø DEA Form 222 or CSOS

ARCOS Transactions

Correction Number

- ∅ Needed for EDI (text file) upload and paper reporting only
- ∅ All uncorrected errors can be queried and corrected in ARCOS Online, no matter reporting method

ARCOS Transactions

Correction Number

- ∅ Can be found on mailed print-outs following submissions; likely discontinued in the future
- ∅ Full list can be obtained by contacting the ARCOS Unit

ARCOS Transactions

Strength

- Ø Purity – when reporting a raw material; combined with Quantity and Unit
- Ø Partial or Combined Package (%) – when reporting a finished package; combined with Quantity of 1

ARCOS Transactions

Transaction Date

- Ø Should represent date of physical change of possession
- Ø EDI (text file) format – use 8-digit date
- Ø Calendar feature – ARCOS Online

ARCOS Transactions

Transaction ID

- Ø Always required – no matter reporting method or type of transaction
- Ø ARCOS Online – automated; adjustable in error corrections and possible duplicates

ARCOS Transactions

Transaction ID

- ∅ Unique to each transaction line in a report, with some exceptions ...
 - ∨ Correction to transaction from previous reporting period
 - ∨ Deleting or adjusting a previously submitted transaction

Error Transactions

- ∅ Transactions that cannot be processed for various reasons; *different from inaccurate transactions*
- ∅ Correction procedure depends on reporting method; however ...
- √ *All error transaction corrections can be made in ARCOS Online!*

Error Transactions

- Ø Correction Number only applies to EDI (text file) upload and paper reporting
- Ø Requests for deletion not likely to be approved; new error deletion feature
- Ø ARCOS Online catches errors up front; only E76 and those related to NDC additions (i.e. still keep an eye on your errors)

Error Transactions

Most Common

- Ø By far, E76 – NDC not found in ARCOS dictionary (42% as of 2/6/2017)
- Ø 2nd most is E16 – Transaction Date outside reporting period (13% as of 2/6/2017)

Error Transactions

Most Common

- Ø 3rd most is E38 – Quantity/Strength issue (9% as of 2/6/2017)
- Ø 4th most is E53 – Order Form missing from transaction (6% as of 2/6/2017)
- Ø *Contact ARCOS Unit for assistance!*

Title 21 U.S. Code and Title 21 Code of Federal Regulations

- ü *Unofficial* versions of 21 U.S.C. and 21 C.F.R. available under “Resources” tab on Diversion Control Division website
- ü Contact Government Printing Office for *official* versions

Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

- ✓ § 827(a)(3) – “Complete and accurate”
- ✓ § 827(b) – “Contain such relevant information as may be required by ... the Attorney General”; “Maintained separately from all other records”

Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

- ✓ § 827(b) – “Readily retrievable”; “Kept and available, for at least two years, for inspection and copying”

Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

- ✓ § 843(a)(4)(A) – Corresponding violations to 21 U.S.C. § 827 ... “Furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed”

Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

✓ § 843(a)(4)(A) – Corresponding violations to
21 U.S.C. § 827 ...

- § Administrative actions
- § Fines and penalties
- § Loss of registration

Title 21 U.S. Code and Title 21 Code of Federal Regulations *21 C.F.R.*

- ✓ § 1304.33 – ARCOS reporting requirements; who reports, what is reported, when are reports due; types of transactions and excepted or exempted transactions

Title 21 U.S. Code and Title 21 Code of Federal Regulations *21 C.F.R.*

- ✓ § 1304.04(a) – “Inventory and other records required to be kept ... must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying”

Title 21 U.S. Code and Title 21 Code of Federal Regulations *21 C.F.R.*

- ✓ Note regarding record retention: If State Law requires a longer retention period, it is expected that records for that period will be available

(citing 21 C.F.R. § 1307.02)

References and Resources

- ü “Resources” tab on Diversion Control website ...
 - ✓ Controlled Substance Schedules
 - ✓ 21 U.S.C. and 21 C.F.R. (unofficial)
 - ✓ Links to other agencies

References and Resources

- ü **ARCOS section of Diversion Control website (under “Reporting” tab) ...**
 - ✓ **ARCOS Registrant Handbook**
 - ✓ **ARCOS Online system**
 - ✓ **Account request forms**
 - ✓ **Announcements**

References and Resources

- ü ARCOS section of Diversion Control website (under “Reporting” tab) ...
 - ✓ Formatting guidelines
 - ✓ NDC dictionary (text file)
 - ✓ Retail Summary reports
 - ✓ Participant Info Update Form
 - ✓ FAQs

References and Resources

ARCOS Registrant Handbook

- ✓ Section 5 – Transaction Records, including Transaction Codes
- ✓ Section 6 – Manufacturing
- ✓ Section 7 – Deleting, Adjusting, and Inserting
- ✓ Appendices 1 & 2 – Matrices for types of transactions

References and Resources

Diversion Control Website

- ✓ Contact information; addresses, phone numbers, email addresses
- ✓ Upcoming events and presentations from previous events

References and Resources

Food and Drug Administration

- ✓ Drug Registration and Listing
- ✓ EDRLS@fda.hhs.gov
- ✓ Obtain labeler code; other NDC related questions

References and Resources

DailyMed

- ✓ National Library of Medicine
- ✓ Current drug products; labels and detailed product information
- ✓ Submissions from Food and Drug Administration
- ✓ <https://dailymed.nlm.nih.gov>

References and Resources

ARCOS Unit

- ✓ Phone: 202-307-8600
- ✓ Email: ARCOS_Unit@usdoj.gov
- ✓ Fax: 202-307-8612

Questions?

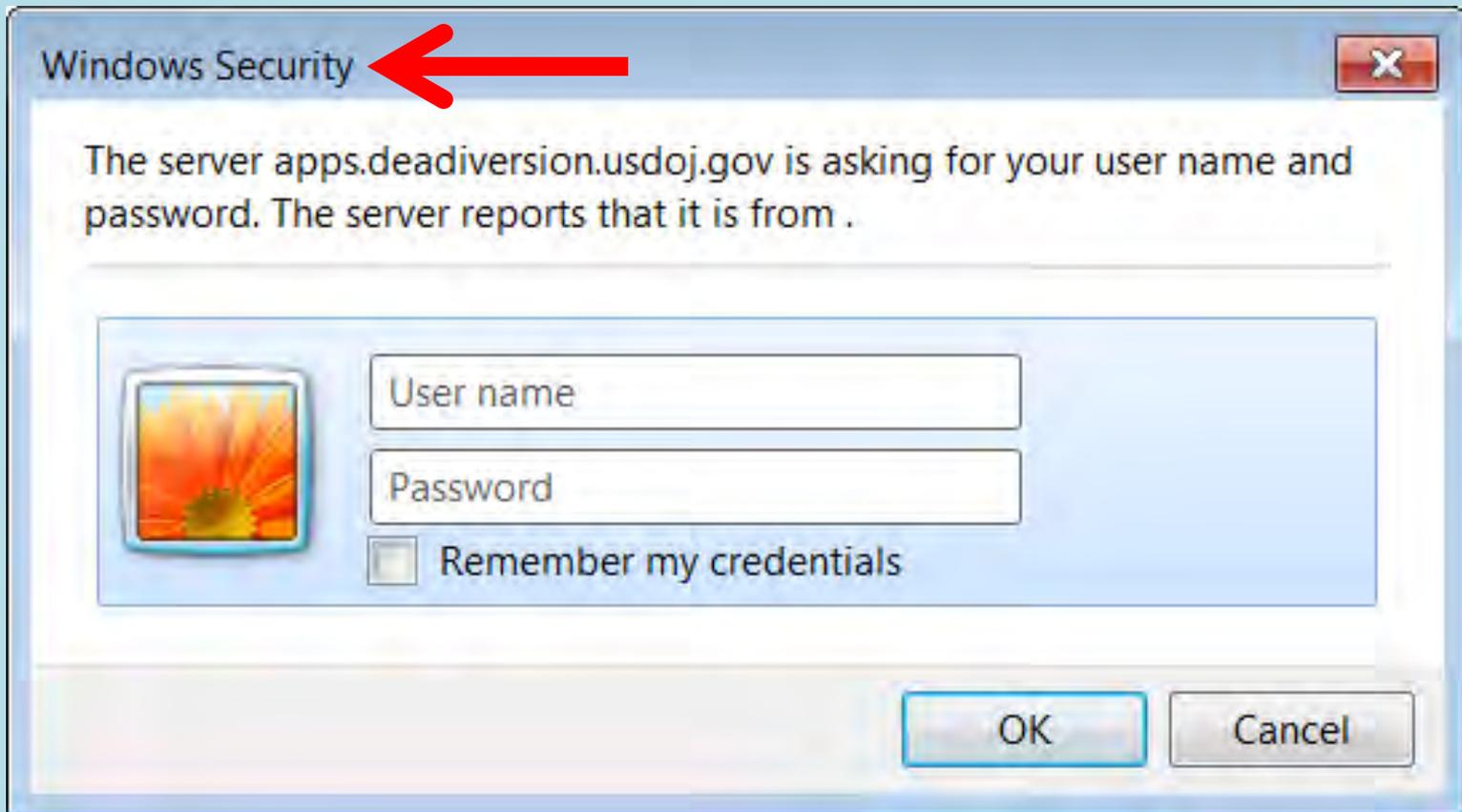
Reporting By Text File

EDI Upload

- ∅ Manual ARCOS EDI Upload:
 - ✓ <https://apps.deadiversion.usdoj.gov/arcos-edi/>
- ∅ Automated ARCOS EDI Upload:
 - ✓ <https://apps.deadiversion.usdoj.gov/arcos-edi/FileUploadManager>

Reporting By Text File

EDI Upload



Reporting By Text File

EDI Upload



EDI Reporting Upload Page

[Help](#)

Select Files To Upload

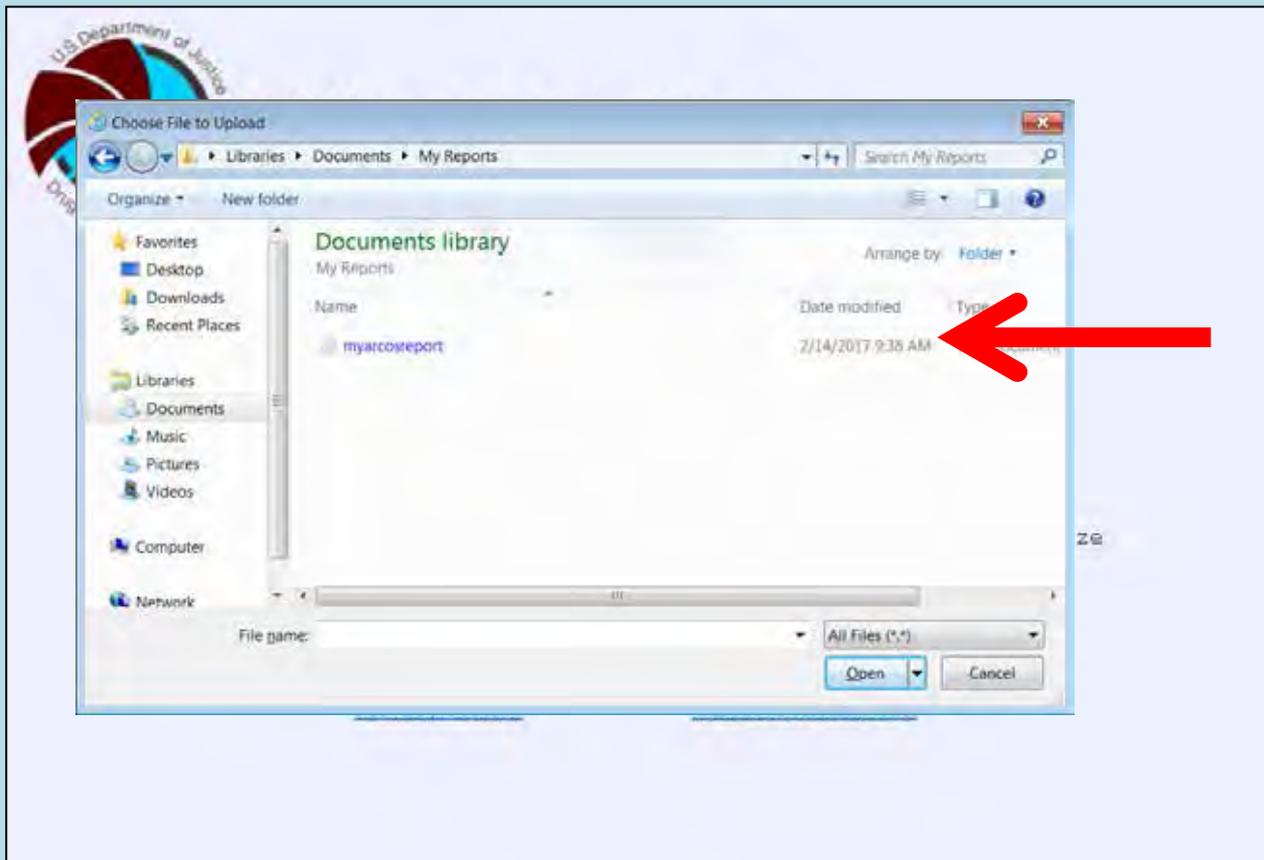
<input type="text"/>	<input type="button" value="Browse..."/>

The upload time of your file(s) will vary depending on the size of the file(s) you attached and your connection speed. Please be patient and press the "Submit" button only once.

[Privacy Notice](#) [Under Construction](#)

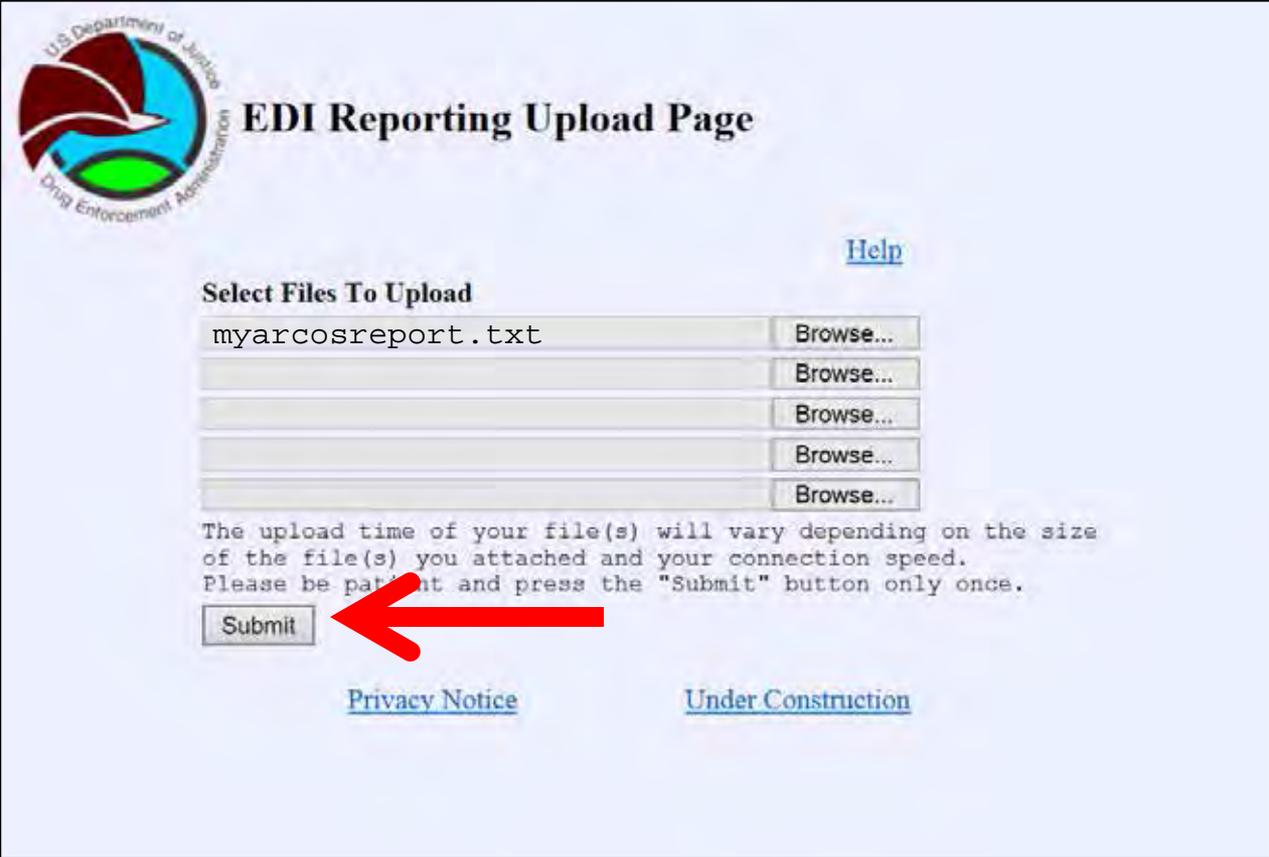
Reporting By Text File

EDI Upload



Reporting By Text File

EDI Upload



The screenshot shows a web interface for uploading EDI reports. At the top left is the logo of the U.S. Department of Justice Drug Enforcement Administration. The page title is "EDI Reporting Upload Page". There is a "Help" link in blue. Below that is a section titled "Select Files To Upload" with five rows. The first row contains the filename "myarcosreport.txt" and a "Browse..." button. The other four rows are empty with "Browse..." buttons. Below the file selection area is a paragraph of text: "The upload time of your file(s) will vary depending on the size of the file(s) you attached and your connection speed. Please be patient and press the 'Submit' button only once." A red arrow points to the "Submit" button. At the bottom, there are two links: "Privacy Notice" and "Under Construction".

 **EDI Reporting Upload Page**

[Help](#)

Select Files To Upload

myarcosreport.txt	Browse...
	Browse...
	Browse...
	Browse...
	Browse...

The upload time of your file(s) will vary depending on the size of the file(s) you attached and your connection speed. Please be patient and press the "Submit" button only once.

[Privacy Notice](#) [Under Construction](#)

Reporting By Text File

EDI Upload

[ARCOS Online Reporting System](#)

[Announcing ARCOS Online \(PDF\)](#)

[Additional Enhancements to ARCOS Online \(PDF\)](#)

[Electronic Data Interchange \(EDI\) Program](#)

[Download ARCOS EDI Request Form \(PDF\)](#)

[ARCOS Participant Information Update Form \(PDF\)](#)

[Reports Required by 21 CFR](#)

[Submit a Tip to DEA](#)

[Year-End Reports](#)

Resources:

[ARCOS Registrant Handbook \(or Download PDF version\)](#)

[National Drug Code Dictionary \(TEXT\)](#)

[Download Readme NDC Dictionary Instructions \(TEXT\)](#)

[Retail Drug Summary Reports](#)

[Questions & Answers](#)

[ARCOS Reporting Notices](#)

[Background: What is ARCOS and What Does it Do?](#)

[ARCOS Bulletins](#)

[Year 2000 Formatting Changes](#)



[Background: What is ARCOS and What Does it Do?](#)

Reporting By Text File

EDI Upload

THE TRANSACTION RECORD - AUTOMATED REPORTERS

(Year 2000 Format beginning January 1, 1999)

(Example Data)	FIELD NAME	COLUMN POSITION
AA9999999	REGISTRANT NUMBER	1-9
P	TRANSACTION CODE	10
D	ACTION INDICATOR	11
000543751**	NDC NUMBER	12-22
00000002	QUANTITY	23-30
4	UNIT	31
BB9999999	ASSOCIATE REGISTRANT NUMBER	32-40
000453890	ORDER FORM NUMBER	41-49
01311997	TRANSACTION DATE (mmdyyyy)	50-57
91070022	CORRECTION NUMBER	58-65
0900	STRENGTH	66-69
0000000088	TRANSACTION IDENTIFIER	70-79
	(Leave Blank)	80

Col.

10 11 12 23 31 32 41 50 58 66 70 80
AA9999999PD000543751**000000024BB9999999000453890013119979107002209000000000088

Changes:

The TRANSACTION RECORD format for automated reporting has been modified for ARCOS-2. The new format has been adopted to ensure compliance with Year 2000 requirements and includes the following changes:

1. The *Transaction Date* field has been expanded to a 4 digit year. Each field following the *Transaction Date* has been shifted to the right 2 positions/columns.
2. The *Document Id* field has been eliminated (Col. 78-80).
3. Column 80 must contain a Blank.
3. **Effective Date: January 1, 1999.**

Reporting By Text File

EDI Upload

THE CONTROL RECORD - AUTOMATED REPORTERS

(Year 2000 Format beginning January 1, 1999)

(Example Data)	<u>FIELD NAME</u>	<u>COLUMN POSITION</u>
AB9999999	REPORTING REGISTRANT	1-9
*	ASTERISK	10
01311999	LAST DAY OF REPORTING PERIOD (mmddyyyy)	11-18
Q	REPORTING FREQUENCY (M or Q)	19
AA9999999	CENTRAL REPORTER <input type="checkbox"/> S NUMBER	20-28

Col.

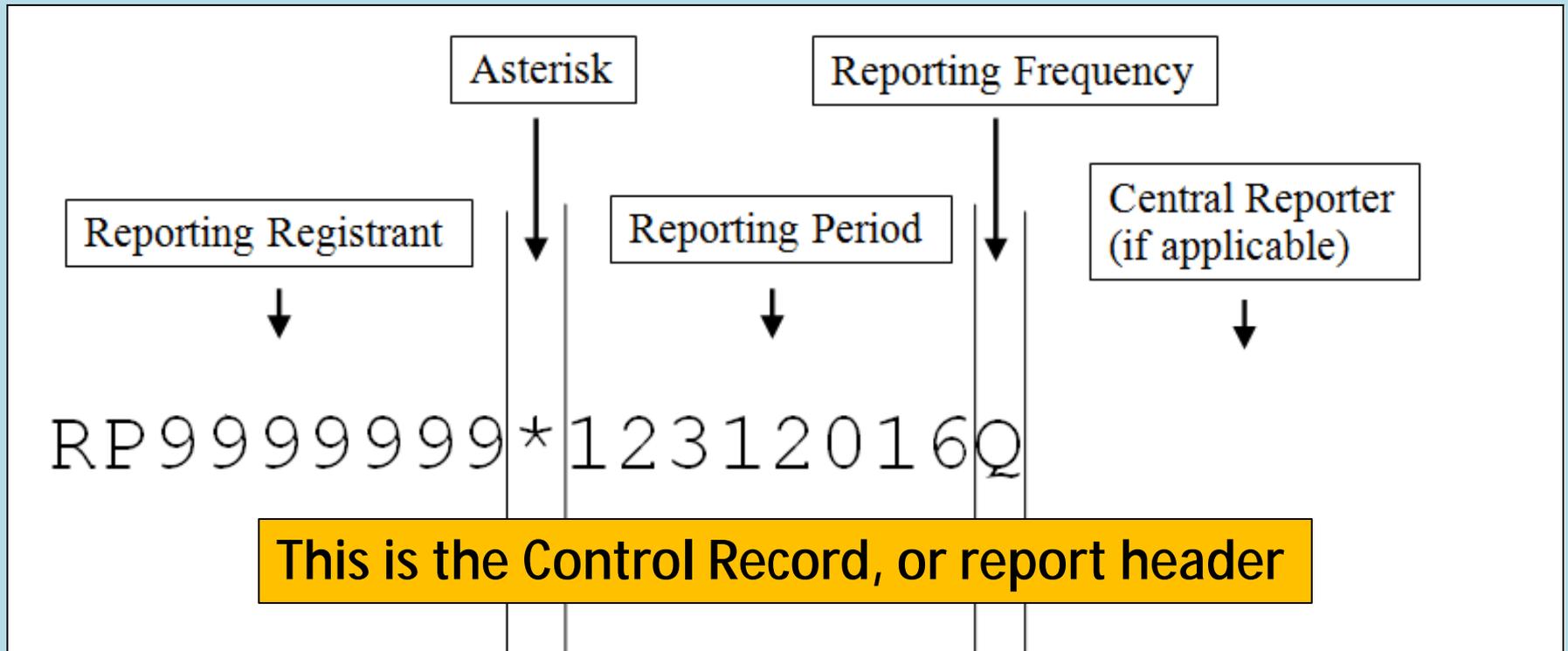
¹AB9999999^{10 11}*^{19 20}QAA9999999

Changes:

The *Last Day of Reporting Period* field has been modified to include the 4-digit year.

Reporting By Text File

EDI Upload



Reporting By Text File

EDI Upload

Reporting Registrant	NDC Number	Quantity	Trans. Code	Action Ind.	Unit	Assoc. Registration Number	Order Form Number	Trans. Date	Correction Number	Strength	Trans. ID	Blank in Col. 80
RP9999999P	12345012301	00000002				RB8888888	161234567	10012016		1000	0000000001	
RP9999999S	02468024602	00000004				RS7777777	162468246	11152016		1000	0000000002	
RP99999993	12345012301	00000002						12312016		1000	0000000003	

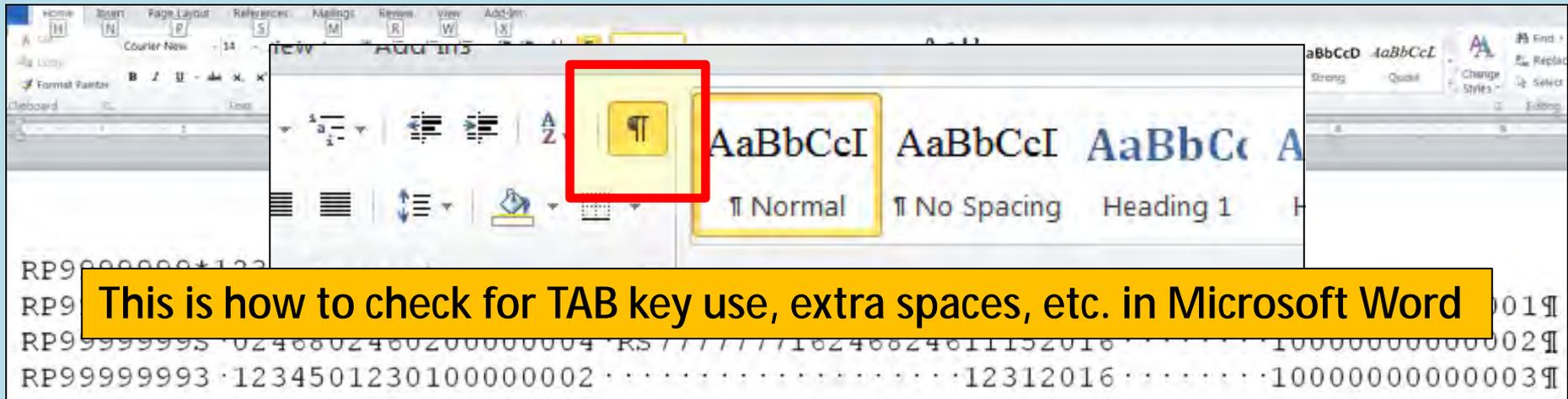
These are the Transaction Records that will appear below the Control Record

Reporting By Text File

EDI Upload

```
RP99999999*12312016Q  
RP99999999 1234501230100000002 RP9999999916123456710012016 100000000000001  
RP99999999 1234501230100000002 12312016 100000000000002  
RP999999993 1234501230100000002 12312016 100000000000003
```

Sample of what a text file report would look like – Control Record plus Transactions



Reporting By Text File

EDI Upload

```
RP99999999*12312016Q␣  
RP99999999P·1234501230100000002·RB8888888816123456710012016·····10000000000001␣  
RP99999999S·0246802460200000004·RS777777716246824611152016·····10000000000002␣  
RP999999993·1234501230100000002·····12312016······00000000000003␣
```

```
016 ······1000000000000  
016 ······1000000000000  
·····→1000000000000
```

Reporting By Text File

EDI Upload

- Ø Saved in plain ASCII text format
- Ø File extension must be .txt
- Ø If Notepad, change “encoding” to ANSI and save file
- Ø Must be uploaded to process

Reporting By ARCOS Online

Ø Stay tuned for live demo!!