

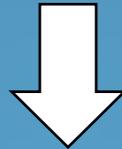
AUTOMATION OF REPORTS AND CONSOLIDATED ORDERS SYSTEM



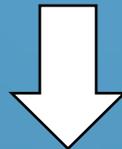
ARCOS Unit
Registration & Program Support Section
Office of Diversion Control
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About the ARCOS Unit

Drug Enforcement Administration



Office of Diversion Control



Registration and Program Support



ARCOS Unit

ARCOS Reporting

Title 21 U.S. Code, Section 827

Manufacturers and Distributors are required to report controlled substances transactions to the Attorney General. The Attorney General delegates this authority to the Drug Enforcement Administration.



*Title 21 Code of Federal Regulations,
Section 1304.33*

ARCOS Reporting

Title 21 Code of Federal Regulations, Section 1304.33

Manufacturers of bulk and/or dosage form controlled substances must report:

- *Acquisitions and Dispositions*
 - All controlled substances in Schedules I and II
 - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III

ARCOS Reporting

Title 21 Code of Federal Regulations, Section 1304.33

Manufacturers of bulk and/or dosage form controlled substances must report (cont'd):

- *Inventories and Manufacturing Activities*
 - All controlled substances in Schedules I and II
 - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III
 - Selected psychotropic controlled substances in Schedules III & IV (*see 21 C.F.R. § 1304.33(d)*)

ARCOS Reporting

Title 21 Code of Federal Regulations, Section 1304.33

**Distributors and Reverse Distributors of
controlled substances must report:**

- *Inventories, Acquisitions and Dispositions*
 - All controlled substances in Schedules I and II
 - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III

ARCOS Reporting

Also Reported:

- **No activity for the reporting period**
- **No end-of-year inventory**
- **In-process end-of-year inventory**
- **Theft and loss of ARCOS reportable materials**
- **Returns**
- **Waste**
- **Destruction**
- **Sampling**

Questions? Contact the ARCOS Unit

ARCOS Reporting: Methods of Reporting

Electronic Reporting

- EDI (text file) upload
- Phase-out of PC Field Edit software
- Introduction of ARCOS Online
- EDI account needed for all electronic reporting

Manual Reporting

- DEA Form 333
- Data entry = longer processing time
- Good back-up option

ARCOS Reporting: Frequency and Status

Reporting Frequency:

- Ø Quarterly
- Ø Monthly
- ✓ *Inventory and Manufacturing Activities are included in the 4th Quarter or December Filing; there is no separate annual ARCOS report*

Reporting Status:

- Ø Single and Central Reporting
- Ø Central Reporting requires authorization

All reports are due the 15th of the month following the end of the reporting period; the ARCOS Unit cannot grant extensions

ARCOS Reporting: Formatting

- **ARCOS Online = web-based, fillable fields**
- **EDI/Text File Upload = 80-character string**
- **Paper Form 333 = handwritten, fillable fields**

ARCOS Reporting: Formatting

**** www.DEAdiversion.usdoj.gov ****

- **Control Record = Section 4 of ARCOS Handbook**
- **Transaction Record = Section 5 of ARCOS Handbook**
- **80-Character String = “Year 2000 Formatting Changes”**

ARCOS Reporting: Manufacturing

United Nations (UN):

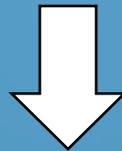
- **Single Convention on Narcotic Drugs (1961)**
- **Convention on Psychotropic Substances (1971)**
- **United States is required to provide yearly manufacturing statistics to the UN**



Reports on Manufacturing Activities to ARCOS are required on an annual basis. (Refer to Section 6 of the *ARCOS Registrant Handbook* for additional guidance)

ARCOS Reporting: Manufacturing

Repackaging and **Relabeling** is considered by DEA to be Manufacturing and, therefore, requires a Manufacturing registration ...



Contact the Food and Drug Administration (Drug Registration and Listing) to obtain a unique labeler code: **EDRLS@fda.hhs.gov**

ARCOS Reporting: National Drug Codes (NDCs) and Product Information

In order for transactions to be processed, the National Drug Code (NDC) associated with the product must be in the ARCOS dictionary ...

... The ARCOS Unit needs the drug label (preferred) from the *original manufacturer* or detailed product information or a copy of the label from the ARCOS reporter for all ARCOS reportable materials

- **Email: ARCOS_Unit@usdoj.gov**
- **Fax: 202-307-8612**
- **Upload: ARCOS Online**

ARCOS Reporting: National Drug Codes (NDCs) and Product Information

Generic (“G” number) NDCs can be used under some limited circumstances:

- **Reverse Distributors ... Reporting the acquisition of products for destruction, along with the actual destruction**
- **Import/Export documentation**
- **Manufacturing; Research and development**
- **Non-commercial activity**

Contact the ARCOS Unit for a listing

Common Issues: Strength and Quantity

- **Raw material** – Quantity, Unit, and Strength used to report weight or volume, along with purity
- **Finished package** – Quantity used to indicate the number of packages represented by the NDC
- **Partial or combined package** – Quantity must be 1, and Strength indicates percent of package

Common Issues: National Drug Codes (NDCs)

- **Most common ARCOS error = E76, NDC not in the ARCOS dictionary**
- **Formatting of NDCs for ARCOS reporting must be 5 – 4 – 2 ... Zero fill at the beginning of each section**
- **Attempting to report non-reportable or non-scheduled materials**
- **Inner versus outer package NDCs – be careful to use the correct one**

Common Issues: Associate Registrant

- **The Associate Registrant cannot be the same as the reporter's registration number (i.e. you cannot report a sale or purchase to or from yourself)**
- **When another company (i.e. customer, supplier, etc.) has multiple registration numbers, be sure to use the correct one**

Common Issues: Action Indicator

- Action Indicator “D” *cannot* be used to delete an *error transaction*; error transactions must be corrected before they can be adjusted or deleted
- A transaction containing Action Indicator “A” must be accompanied by a transaction containing Action Indicator “D” in order to adjust a previously submitted, processed transaction

Error Transactions

Correction Number:

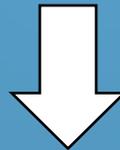
- Only continues to apply to EDI (text file) and paper reporting
- Eliminated when correcting errors in ARCOS Online

Error Notifications:

- If reporting electronically, check all uncorrected errors using ARCOS Online
- Only paper reporters will continue receiving paper error report print-outs

Error Transactions

Requests for deletion of errors are handled on a case by case basis with multiple factors taken into consideration – *it is always best to correct errors on your own if at all possible*



Contact the ARCOS Unit for assistance with error corrections

Other Things to Remember

- **EDI upload confirmation is not a receipt that the report has been filed and processed**
- **Only the Deputy Assistant Administrator in charge of the Office of Diversion Control can grant exceptions to ARCOS reporting**
- **Reports must be filed for both no activity and no end-of-year inventory (in order to receive credit)**
- **ARCOS end-of-year inventory is separate from YERS report**

Other Things to Remember

- **“Complete and accurate” reporting as required by the Controlled Substances Act**
- **Record retention = two years; however, if state exceeds two years, keep ARCOS records based on state requirements**
- **It is the responsibility of the reporter to keep contact information up to date; please include labeler code(s) if applicable**

Other Things to Remember

- **Transaction Date should reflect the date the product physically left or arrived in possession (Note: If transaction occurred between two ARCOS reporters, it is understood that the dates will be different)**
- **A report containing error transactions contains transactions that cannot be processed and, therefore, the report is not “complete and accurate”**

ARCOS Online – Released November 2015

- **Initial phase replaced old PC Field Edit software**
- **Latest updates include ability to query all uncorrected errors, update contact information, and change password (*April 2016*)**
- **Elimination of Action Indicators to adjust, delete, or add transactions**
- **Ability to upload labels or product documentation to the ARCOS Unit for review**
- **Errors detected as transactions are entered**
- **More updates to come!!!**

ARCOS Reporting: Resources

- **ARCOS Registrant Handbook, specifically:**
 - **Section 5** – Transaction Record, including Transaction Codes
 - **Section 6** – Manufacturing activities, including Transaction Codes for Manufacturing
 - **Section 7** – Corrections and adjustments
 - **Appendices 1 & 2** – “Matrix” of required fields by Transaction Code

ARCOS Reporting: Resources

- Office of Diversion Control website (www.DEAdiversion.usdoj.gov), specifically:
 - **“Resources” tab** – unofficial versions of Title 21 U.S.C. and Title 21 C.F.R.; also Controlled Substance schedules
 - **“Reporting” tab** – where to access the ARCOS section of the website
 - **“About Us” tab** – various contact information for the Office of Diversion Control

ARCOS Reporting: Resources

- **DailyMed – National Library of Medicine**
 - **Resourceful for obtaining labels and detailed product information of products currently on the market**
 - ***<https://dailymed.nlm.nih.gov/>***

Questions?



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