Guidance for Industry

Medical Device Reporting – Alternative Summary Reporting (ASR) Program

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U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Reporting Systems Monitoring Branch
Division of Surveillance Systems
Office of Surveillance and Biometrics

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Reporting Systems Monitoring Branch, HFZ-533, 1350 Piccard Drive, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Reporting Systems Monitoring Branch at 301-594-2735.

Additional Copies

Additional copies are available from the World Wide Web home page: http:/www.fda.gov/cdrh/osb/guidance/315.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number (315) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Medical Device Reporting – Alternative Summary Reporting (ASR) Program[1]

This document contains information about the Alternative Summary Reporting (ASR) Program, created under the authority of 21 CFR Part 803.19. You (device manufacturers) should use this information as a guide for requesting approval to participate in the ASR program and for preparing ASR reports. This document replaces the instructions and conditions for *Summary Reporting of Medical Device Adverse Events* that were contained in the July 31, 1997, FDA Memorandum to Manufacturers.

I. THE ALTERNATIVE SUMMARY REPORTING PROGRAM :

On October 1, 1999, we (FDA) instituted new methods for the collection of summary reporting data. Adverse events included in summary reports should be submitted in a line-item format, reporting selected data elements by individual adverse event, rather than by the previous method of grouping adverse events by device identification number.

You should provide a unique identification number for each line-item event included in the ASR report. This unique identification number should match the applicable event in the firm's complaint file. Information that must be included in a line item ASR report is provided in Attachment A. General instructions for line-item reporting are provided in Attachment B and examples of a line-item report are provided in Attachments C and D to help describe what data is to be presented in the report. The examples may be used as templates for preparation of the line-item ASR reports.

In order to reduce supplemental reports, we have provided specific instructions in Attachment B which allow the firm more time to gather the essential ASR data elements when this information is not available at the time the quarterly report is due.

The following FDA forms and instructions referred to in this letter are available on the FDA website at www.fda.gov/cdrh/mdr.html:

- *Instructions for Completing Form 3417 Medical Device Reporting Baseline Report*, revised March 31, 1997
- *MDR Guidance Document Remedial Action Exemption - E1996001*, dated July 30, 1996
- *Instructions for Completing Form 3500A with Coding Manual for Form 3500A*, dated December 14, 1995
- *Addendum to the Instructions for Completing Form 3500A with Coding Manual for Form 3500A, dated December 14, 1995*, dated June 9, 1999

[1] [1]This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. YOUR EXEMPTION REQUEST:

- All requests to participate in the ASR program must be in writing and contain the following information, as required by 21 CFR Part 803.19(b):
    - A statement notifying FDA of the request to participate in the ASR program.
    - An explanation of why the request is justified.
    - Identification of the device manufacturer.
    - The product classification code(s) for the device(s) that will be included in the ASR report. (For example, KOD – Foley Catheters).
    - The reporting site registration number, contact person and address of the firm who will be submitting the ASR reports to the FDA.

Requests for approval to participate in the Alternative Summary Reporting (ASR) program should be mailed to:

Reporting Systems Monitoring Branch, HFZ-533
Division of Surveillance Systems
Office of Surveillance and Biometrics
1350 Piccard Drive
Rockville, MD 20850

If you have any questions, please contact the ASR Coordinator, Reporting Systems Monitoring Branch (RSMB), by telephone at (301) 594-2735 or by fax at (301) 827-0038.

III. BASELINE REPORTS:

Because baseline reports are a critical part of the new ASR program, it is very important that your firm's baseline information is correct and up-to-date.

Your ASR approval letter will contain a printout of all the baseline report data we have on file for the reporting registration site number and product classification code(s) included in your request letter. This information will come from Parts I and II of FDA form 3417 that are relevant to the ASR summary reporting program. Please review this printout carefully to ensure that:

a) an Initial Baseline or Annual Update form 3417 for each device identifier that will be included in future ASR reports is on file;
b) Part I of your report on Baseline form 3417 lists the correct reporting site registration number and contact information in items 2a-g and 3a-g; and

c) Part II of your Baseline form 3417
    - lists the correct manufacturing site registration number and address in item 1a-b; and
    - lists the correct device identifier(s) in items 4, 5 or 6 of the initial baseline report, annual update or, for device families, the attached matrix submitted with the initial baseline report.

Please note:

- the device identifier is the individual model, catalog or other number used by your firm to identify the individual device.
- the device identifier should be listed in the exact manner you will always use to report events in ASR for that device. (e.g., model 2000 A is not the same as Model 2000A, Model 2000/A or Model 2000-A, etc.)
- for cases where you may have previously identified to FDA a unique device by more than one device identifier, select only one of those identifiers (model, catalog or other number) to be used for ASR purposes and inform FDA of your choice.

You should correct the baseline information and provide any missing initial baseline and/or annual update information for each candidate ASR device by the date specified in your approval letter. This information should be sent to

Alternative Summary Reporting Coordinator
Reporting Systems Monitoring Branch, HFZ-533
Division of Surveillance Systems
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

Initial baseline reports and subsequent annual updates are required by 21 CFR Part 803.55 for devices involved in adverse events that are submitted to the FDA on form 3500A for the first time. The Initial Baseline report or Annual Update is provided to the FDA using form 3417. This also applies to devices under ASR. Therefore, baseline information must be on file for each device identifier included in your quarterly report submissions. If an event involves a new device identifier that you will report to us for the first time under the ASR program, you must submit the baseline report to us thirty (30) days prior to the submission of the first ASR report involving that device. Specific rules are as follows:

a) There must be an Initial Baseline report or Annual Update on form 3417 filed with the FDA for any new device identifier that was not included on a previous baseline or update report submitted under the requirements of 803.55. Make sure that the new device identifiers are listed on form 3417 exactly as they will appear in your ASR reports.
b) You must notify us of any updates you make to previously submitted Initial Baseline reports or Annual Updates for device identifiers included in your ASR reports.

c) New Initial Baseline reports or Annual Updates are to be mailed to FDA at the following address in a mailing container marked "ASR Baseline Reports":

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

IV. ALTERNATIVE SUMMARY REPORTING (ASR) EXEMPTION CONDITIONS:

1. This exemption from the individual event reporting requirements of sections 803.50 and 803.52 and the availability of alternative summary reporting applies to (*We will specify the specific devices and adverse event types)*.

2. The events subject to this exemption are reported in a line-item ASR format to the FDA every quarter. The ASR reports must contain the data listed in Attachment A. These data are a subset of the information required by 21 CFR 803.52, or can be derived from that information.

3. ASR reports are due:

   (a) January 31 for events that would otherwise be required to be reported during the preceding period between October 1 and December 31;
   (b) April 30 for events that would otherwise be required to be reported during the preceding period between January 1 and March 31;
   (c) July 31 for events that would otherwise be required to be reported during the preceding period between April 1 and June 30;
   (d) October 31 for events that would otherwise be required to be reported during the preceding period between July 1 and September 30.

   We will inform you when your first ASR report is due to cover events that would otherwise be reported during the specified reporting period.

4. You are still required to investigate and evaluate complaints as specified in 21 CFR 803.18(e) and 803.50 and to establish and maintain MDR event files as specified in 21 CFR 803.18 for events covered by this exemption.

5. If any of the events to be summarized involves a device that is the subject of a remedial action, then your firm may consider using the remedial action exemption contained in the "MDR Guidance Document: Remedial Action Exemption - E1996001" dated July 30, 1996. If you decide to use it, you must submit at least one individual event report on form 3500A for the suspect device with your Remedial Action Exemption (RAE) Notification. Subsequent events involving the device(s) and problem do not have to be submitted to the FDA under the conditions of the RAE notification.

6. Baseline reports must be submitted as required by 21 CFR 803.55 for all device identifiers (model, catalog or other number) included in an ASR report. New and amended baseline reports must be submitted to the FDA thirty (30) days prior to the due date of your firm's first quarterly ASR report submission containing the new device identifiers. (See specific instructions in Part III - Baseline Reports).

7. This exemption may be revoked or modified in writing if FDA determines that protection of the public health justifies the modification or a return to the requirements of 21 CFR 803.50 and 803.52 as provided in 21 CFR 803.19.

8. FDA reserves the right to request the submission of an individual event report on Form 3500A for any event(s) included in an ASR report if it determines that it needs the report(s) to evaluate the event(s).

V. TYPES OF EVENTS NOT COVERED BY THIS EXEMPTION:

The following types of events are not covered by this exemption and must be reported as specified in 21 CFR 803.50 and 803.52:

a) Events that require the submission of a 5-day report under the requirements of 21 CFR 803.53.
b) Events where the device, other than a mechanical heart valve (product code LWQ), may have caused or contributed to a death.
c) Events involving mechanical heart valves (product code LWQ) where the implant duration was less than five (5) years.
d) Events involving a permanent pacemaker electrode (product code DTB) where the manufacturer confirmed a device failure.
e) Events involving a Class III device that has been marketed under an approved PMA for less than two (2) years.
f) The occurrence of multiple serious injuries as a result of a single event or device failure.
g) Events associated with explosion or fire.
h) Events that the manufacturer considers unusual, unique or uncommon and that would be given an evaluation conclusion code of 66-Unusual event (see Instructions for Completing Form 3500A with Coding Manual for Form 3500A, dated December 14, 1995).

ATTACHMENT A
INFORMATION TO BE INCLUDED IN A LINE-ITEM ALTERNATIVE SUMMARY REPORT (ASR)

PART 1 – COVER SHEET (See example in Attachment C)

Please provide the following data::

1. Date of the ASR report. Use as 2-digit month/2-digit day /4-digit calendar year. (e.g., 04/30/2000).
2. ASR reporting authorization number (assigned by the FDA).
3. Name of the manufacturer.
4. Name of the reporting site if different from manufacturer name.
5. Registration number of the site making the report, as listed in the ASR authorization letter.
6. Address of the reporting site (street, city, state or country, and zip code or mail code).
7. Name and signature of the report contact (i.e., person submitting the report).
8. Telephone and fax number of the report contact person (include the country and city codes if the contact is a foreign manufacturer).
9. E-mail address of the report contact person, if available.

PART II - REPORTABLE EVENTS (See example in Attachment D)

Please provide the following data on each Part II page:

1. Registration number of the site making the report, as listed in the ASR authorization letter.
2. Reporting period covered by the ASR report (beginning date and ending date). Use a 2-digit month/2-digit day /4-digit calendar year. (e.g., 01/01/2000 – 03/31/2000).
3. Product classification code of the device. (e.g., KOD – Foley Catheters).
4. Page number listed with total number of Part II pages included in the ASR report (e.g., Page 1 of 4).

Please provide the following data for each eligible ASR report event received during the applicable reporting period:

1. Unique report identification number. This is the internal identification number assigned by the manufacturer to the individual complaint and should be provided on the Part II pages in sequential order. **Do not use hyphens, spaces or other delimiters in the identification number. The number can be alphanumeric or numeric with a maximum of 12 characters in length.** See the examples in Attachment D.

   Please note**:** that this is the number FDA will use when referring to an individual line-item complaint. It is important that the ID number provided in your ASR report match your firm's original complaint file.)

2. Basic device identifier (model number, catalog number, or other type of identification number) as listed in Part II, items 4, 5 or 6 of the corresponding baseline report.
3. Event report type listed as “D”, “I” or “M” (for death, serious injury or malfunction).
4. Manufacturer aware date. This is the date that the manufacturer became aware of an adverse reportable event and is defined under 21 CFR Part 803.3(c). Use a 2-digit month/2-digit day /4-digit calendar year. (e.g., 01/20/2000).
5. Provide codes for each of the following categories. You may provide more than one code per category but they should be grouped together by category. (These are the codes that are reported in blocks F10, H6 or H11of FDA form 3500A.).

    - Device Problem Code
    - Patient Problem Code
    - Evaluation Results Code
    - Evaluation Conclusion Code

The codes you provide must represent your best knowledge of the adverse event and your firm's evaluation results and conclusion codes. The device and patient problem codes and the evaluation results and conclusion codes are found in the “Instructions for Completing FDA Form 3500A with Coding Manual” dated December 14, 1995 and in the "Amendment to the Instructions for Completing FDA Form 3500A with Coding Manual" dated June 9, 1999.

We do realize that the coding manual is not all-inclusive and there may be cases where your firm cannot easily identify a matching or similar code(s) that would best describe the patient or device problem or the evaluation result and conclusion. If this is the case, please contact the ASR Coordinator prior to the submission of your quarterly report or provide us with a list of the event related terms for which you are having difficulty. We will assist you in identifying an appropriate code(s) or will assign a new code(s) as applicable.

ATTACHMENT B

LINE-ITEM ALTERNATIVE SUMMARY REPORTING (ASR) – GENERAL INSTRUCTIONS

1. Each ASR report should have a completed Part I – Cover Sheet page and Part II – Reportable Events Summary page(s).

2. Each ASR report should contain all of the data elements listed under Part II of Attachment A, presented in a line-item format similar to the examples found in Attachment D.

3. Each line-item will represent one adverse event. If you have 25 adverse events to include in your quarterly ASR report, then you will have 25 individual line-items with the required data.

4. If a single adverse event includes multiple suspect devices, then you must submit a separate line-item for each device covered by this exemption.

5. If multiple product classification codes (e.g. KOD - Foley Catheters and DTB – Permanent Pacemaker Electrode) have been approved under one ASR reporting exemption number, then only one quarterly report is required. However, there should be one complete set of Part II - Reportable Events Summary page(s) for each product code and each set is to be clearly separated from the others.

6. If there were no eligible ASR events received by your firm during the applicable reporting period, then you still should complete and submit a Part I – Cover Sheet, indicating that there were no eligible ASR events received during the reporting period.

7. If your firm is unable to provide all of the required ASR line-item data elements listed in Attachment A Part II, for an event(s) at the time the quarterly ASR report submission is due, do not include it in that submission. Instead, the evaluation of the event(s) should continue throughout the next reporting period. At the end of that reporting period, your firm must submit whatever information is available at that time.

8. If your firm cannot provide evaluation result codes for a line-item event because the suspect medical device will not undergo device testing, you should provide a conclusion code for each event. For the purposes of ASR, we have added several new conclusion codes that should be used to reflect that the suspect medical device was not evaluated. They may be used alone or with any other applicable conclusion code(s) from pages 76-77 of the “Instructions for Completing FDA Form 3500A with Coding Manual” dated December 14, 1995 and page 9 of the "Amendment to the Instructions for Completing FDA Form 3500A with Coding Manual” dated June 9, 1999. Please add the following evaluation conclusion codes to your coding manual:

92 - Device not returned - no evaluation will be performed.
93 - Device problem already known - no evaluation will be performed.
94 - Device received in a condition that made analysis impossible - no evaluation will be performed.

9. If the suspect medical device will not be evaluated and your firm uses reserve samples to perform device testing, then the following conclusion code should be used in conjunction with any other applicable conclusion codes that reflect the outcome of the device testing of the samples. We also expect your firm to provide the applicable evaluation results codes that best reflect the test results. (Only one line item needs to be provided even if you evaluated more than one reserve sample).

   95 - Device not returned - reserve samples evaluated.

10. Corrections:

    Corrections to line-item data contained in an ASR report should be submitted on a Part II - Reportable Events page. The corrected Part II page(s) must be submitted as a separate attachment with your firm's next scheduled ASR report submission. Furthermore,

    a) Each corrected Part II - Reportable Events page(s) should list, at the top of the page, the applicable ASR report exemption number and reporting site registration number.
    b) Each corrected line-item must include all of the required ASR data elements, including the most recent and correct values. (We will replace the previously submitted line-item data elements with the corrected version).

ATTACHMENT C

MANUFACTURER ALTERNATIVE SUMMARY REPORT (ASR)

PART I - Cover Sheet (EXAMPLE)

DATE OF ASR REPORT: _____
(MM/DD/YYYY)

ASR REPORTING AUTHORIZATION NUMBER: _____

MANUFACTURER NAME:_____

REPORTING SITE COMPANY NAME: _____
(if different from manufacturer name)

REGISTRATION NUMBER (Reporting Site): _____

STREET (Reporting Site): _____

_____

CITY (Reporting Site):_____

STATE (Reporting Site): _____ **ZIP (Reporting Site)**: _____
(or COUNTRY) **(or POSTAL CODE)**

CONTACT NAME (Person submitting report): _____

SIGNATURE: _____

TELEPHONE NO: (_____) _____**ext**._____ or **FOREIGN TELEPHONE NO**: _____
(including area code) **(including country & city codes)**

FAX NO: (____) _____ ext. ____ or **FOREIGN FAX NO**: _____
(including area code) **(including country & city codes)**

E-Mail Address:_____

❑ **THERE WERE NO ELIGIBLE ASR EVENTS RECEIVED DURING THIS REPORTING PERIOD**

ASR reports are to be mailed to the following address in an envelope or other mailing container marked "ASR Report":

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

ATTACHMENT D	MEDICAL DEVICE REPORTING (MDR) SUMMARY REPORT - PART II						
ASR Reporting Authorization No:	E2000xxx						
Registration No. (Reporting Site):	1234567						
Reporting Period	From: 01/00/2000		To: 03/31/2000				
Procode:	XXX (insert product classification code here)						
Report Identification Number	Device Identifier (Model #, Catalog #, Other #)	Event Report Type (list as D [death], I [injury], M [malfunction])	Manufacturer Aware Date	Patient Problem Code(s)	Device Problem Code(s)	Evaluation Results Code(s)	Evaluation Conclusion Code(s)
123455678001	123-4567	I	01/10/2000	2045	2340	101	47
				1912	1012	533	54
					1423	174	
123455678002	123-8910	M	01/15/2000	2199	1354	101	47
						545	
123455678003	123-9876	I	02/13/2000	2045	1354	208	78
				2469	1171		79
				1912			
123455678004	456-1234	D	02/22/2000	1802	1354	101	42
				1762	1012	533	54
						174	63
						456	
123455678005	456-5678	M	03/02/2000	2199	1354	101	42

ATTACHMENT D (cont.)		ASR REPORT - EXAMPLE				Page 2 of 2	
		MEDICAL DEVICE REPORTING (MDR) SUMMARY REPORT - PART II					
ASR Reporting Authorization No:	E2000xxx						
Registration No. (Reporting Site)	1234567						
Reporting Period	From: 01/01/2000		To: 03/31/2000				
Procode:	XXX (insert a 2nd. Product classification code here)						
Report Identification Number	Device Identifier (Model #, Catalog #, Other #)	Event Report Type (list as D [death], I [injury], M [malfunction])	Manufacturer Aware Date	Patient Problem Code(s)	Device Problem Code(s)	Evaluation Results Code(s)	Evaluation Conclusion Code(s)
123489768RXY	789-1234	M	01/10/2000	2199	1371	174	42
					1354	101	
						432	
123489769SXY	789-5678	M	01/15/2000	2199	1354	207	79
						208	
123489769TXY	789-1443	D	02/13/2000	1802	1169	131	63
				1917	1193		
				1762			
123489769XXY	790-5660	I	03/02/2000	2485	1025	708	74
				1776			