Pilot Multipurpose Audit Program (PMAP)
Questions and Answers related to the Pilot

Q1 What is the purpose of the Pilot Multipurpose Audit Program (PMAP)?

A1 The United States and Canada recognize the importance of the role of third parties in the oversight of the medical device industry. Both countries also recognize the benefits of closer regulatory cooperation, as reflected in the 2003 Memorandum of Understanding between the US Food and Drug Administration (FDA) and the Health Products and Food Branch of Health Canada (HC) and the broader government-level Security and Prosperity Partnership (SPP), signed in March 2005. The Pilot Multipurpose Audit Program (PMAP) is an important outcome of this evolving regulatory cooperation.

Qualified auditing organizations (AOs) are now capable of performing third party audits/inspections of medical device manufacturers' quality systems that will respectively meet the regulatory requirements of the US and Canada. Multipurpose audits/inspections are already taking place under other programs. Through the PMAP, FDA and HC hope to increase awareness of the advantages of multipurpose audits/inspections currently made possible by AOs operating in the FDA's Accredited Persons (AP) program and HC's Canadian Medical Devices Conformity Assessment System (CMDCAS).

The PMAP is intended to be a vehicle for further regulatory cooperation between our countries and thereby lead to a reduction of regulatory burden on industry. FDA and HC wish to use these multipurpose audits/inspections as a learning opportunity to acquire a better knowledge of auditing/inspection approaches that support regulatory objectives while minimizing regulatory burden.

The PMAP does not add to, delete from, nor alter previously established and published procedures, guidance, and regulations used by FDA's AP program or HC's CMDCAS program.

Q2 What are the advantages of participating in the PMAP?

A2 Manufacturers participating in the PMAP gain the opportunity to be assessed by a single AO to both US and Canadian regulatory quality management system requirements. It is anticipated that this will reduce audit/inspection-related interruptions in the work place and result in resource savings for manufacturers.

AOs participating in the PMAP have the opportunity to better serve their clients by offering a wider range of services that would allow manufacturers to fulfill both US and Canadian regulatory requirements.

As noted above, FDA and HC hope to use experience gained with the PMAP to identify best practices and to promote an enhanced cooperative regulatory approach.

Q3 When does the PMAP start?

A3 The PMAP officially began in September 2006, with the publication of a letter to AOs from both FDA and HC inviting their participation in the Multipurpose Audit Program. Copies of the letter may be found on either of the following web pages:

FDA: www.fda.gov/cdrh/ap-inspection/index.html
HC: www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/index_e.html

Q4 What is the duration of the PMAP and what will happen at the completion of the pilot phase?

A4 The PMAP will progress as a continual improvement effort until such time that sufficient experience has been gained to evaluate the activity. FDA and HC will jointly assess the lessons learned during the pilot to identify best practices and areas for improvement in the conduct of multipurpose audits/inspections. It is anticipated that the results of the PMAP will be initially assessed once ten multipurpose audits/inspections have taken place under the pilot.

Because multipurpose audits/inspections are intended to satisfy different quality management system requirements, key indicators of success may include:

- The level of manufacturer and AO participation; and
- The ability of AOs to demonstrate that their pre-audit/inspection planning, documentation review, on-site assessment, and audit/inspection reporting still conforms to FDA AP and HC CMDCAS program requirements.

FDA and HC will provide feedback, where appropriate, to the AO in order to improve their procedures and performance.

The results of an audit/inspection performed under the pilot phase will not influence the eligibility of the manufacturer to participate in latter phases of the Multipurpose Audit Program. In addition, manufacturers who did not participate in the pilot are free to participate at a later date and will not be faced with any restrictions.

Q5 Will the fees AOs charge manufacturers be controlled by FDA or HC?

A5 No. Neither FDA nor HC will set or control the fees AOs charge manufacturers.

Q6 Will FDA or HC charge participating manufacturers or AOs a fee to participate in the PMAP?

A6 No. Neither FDA nor HC will charge manufacturers or AOs a fee to participate in the PMAP. The pilot is meant to provide a mechanism to acquire knowledge and

learn from the experience of multipurpose audits/inspections, to the benefit of all parties involved.

Q7 As a manufacturer of a medical device that sells in both the US and Canada, what do I have to do to take advantage of the PMAP?

A7 If a manufacturer meets the conditions listed below, that manufacturer is eligible to be part of the PMAP. The manufacturer should:

- Meet both the US FDA and HC definition of a device manufacturer;
- Currently sell a Class II or III device in the US that meets the US definition of a medical device;
- Currently be in possession of at least one valid medical device licence to sell a Class II, III or IV device in Canada; and
- Currently use the services of an AO that is both a Health Canada Recognized Registrar and a US FDA Accredited Person. (Note: FDA and HC will maintain a list of AOs that meet this criterion. This list will be posted on both Regulatory Authorities' web sites.)

Manufacturers interested in participating in the pilot phase should send a letter to both FDA and HC noting their intent to participate in the PMAP and indicating how they meet the above eligibility criteria. Manufacturers can improve the multipurpose audit/inspection process by providing written consent for the sharing of pre-audit/inspection and post-audit/inspection information between FDA and HC. An example of a voluntary information release letter is included in Annex A of this document.

Current information and guidance on third party inspections are available from FDA and HC web sites at:

FDA: www.fda.gov/cdrh/ap-inspection/ap-inspection.html
HC: www.hc-sc.gc.ca/dhp-mps/md-im/index_e.html

Sites that an AO would visit during a multipurpose audit/inspection would include, but are not limited to, sites in North America and overseas where:

- Overall management of the organization takes place;
- Products are designed;
- Assembly takes place;
- Products are packaged and stored;
- Contract sterilization takes place;
- Outsourced processes related to the device are performed by suppliers to the manufacturer;
- Device related complaints and problems are received and reported on; and
- Device related regulatory affairs are performed.

See Annex B for an outline and flowchart of the PMAP application and audit/inspection process.

Q8 As a manufacturer that presently has a registered ISO 13485:2003 quality management system and is also compliant to CFR 21 Part 820, what types of existing HC Recognized Registrar audits or existing FDA AP inspections are acceptable under the PMAP?

A8 Annual HC Recognized Registrar surveillance audits and 3-year re-registration audits, as well as FDA AP inspections that follow the Level I or Level II Quality System Inspection Technique (QSIT), are acceptable under the PMAP.

HC Recognized Registrar related audits that are not acceptable would include:

- Initial ISO 13485:2003 registration audits under CMDCAS;
- Transfer of registration from one AO to another;
- Upgrades to ISO 13485:2003;
- Audits to support an extension to the existing scope of registration; and
- Special "for cause" audits. (For cause audits would be non-routine audits performed by the AO that are intended to address a serious concern the AO may have about the manufacturer.)

Q9 Can a multipurpose audit/inspection replace a previously scheduled HC Recognized Registrar audit or FDA AP inspection?

A9 Yes, a multipurpose audit/inspection may be scheduled and performed for an annual surveillance or re-registration HC Recognized Registrar audit as long as the date of the multipurpose audit/inspection satisfies:

- The HC Recognized Registrar's annual surveillance or 3-year re-registration audit schedule; and
- The FDA AP inspection criteria.

Q10 Will information about the performance of an AO and audit/inspection reports issued under the PMAP be made public?

A10 FDA and HC may share general information about the operation of the PMAP and lessons learned during the course of the pilot. The PMAP does not in any way change current laws, regulations or practices in the US and Canada regarding the release of confidential information.

Q11 Can observers like FDA, HC and Standards Council of Canada (SCC) observe an audit/inspection?

A11 FDA, HC and the SCC reserve the right to observe audits/inspections performed by an AO, whether as part of a multipurpose audit/inspection or not.

Pilot Multipurpose Audit Program (PMAP)
Questions and Answers related to the Pilot

Q12 What is the contact information for this program?

A12 If you have questions, please contact either the US Food and Drug Administration or Health Canada as follows:

David Kalins
Office of Compliance
Center for Devices and Radiological Health
US Food and Drug Administration

9200 Corporate Blvd.
HFZ-300
Rockville MD USA
20850

david.kalins@fda.hhs.gov
(240) 276-0184

Egan Cobbold
Quality Systems Section
Medical Devices Bureau
Therapeutic Products Directorate
Health Canada

Room 1605
Statistics Canada Main Building
150 Tunney's Pasture Driveway
AL 0301 H1
Ottawa ON Canada
K1A 0K9

ISO13485_CMDCAS_SCECIM@HC-SC.gc.ca
(613) 952-8250

Annex B
PMAP Multipurpose Audit Flowchart

MANUFACTURER'S AUTHORIZATION FOR FDA AND HC TO SHARE CONFIDENTIAL COMMERCIAL AND/OR TRADE SECRET INFORMATION

(MANUFACTURER SHOULD PREPARE ON ITS LETTERHEAD)

Melinda K. Plaisier, Assistant Commissioner for International Programs, Office of International Programs United States Food and Drug Administration 5600 Fishers Lane (HFG-1) Rockville, MD 20857

Michael Vandergrift, Director General for Policy, Planning and International Affairs Directorate Health Canada 250 Lanark Avenue Ottawa, ON K1A 0K9

RE: Sharing of Non-Public Information between the Food and Drug Administration and Health Canada concerning *[Insert Name of Manufacturer]* as part of a multipurpose audit/inspection conducted under the Pilot Multipurpose Audit Program

Dear Assistant Commissioner Plaisier and Director General Vandergrift:

On behalf of *[insert name of manufacturer]*, I authorize the United States Food and Drug Administration (FDA) and Health Canada (HC) to share the information described below solely for the purpose of implementing and improving multipurpose audits/inspections. I understand that the information may contain non-public information including, but not limited to, confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331(j), and 5 U.S.C. § 552(b)(4) and, in respect to Health Canada, may include confidential commercial business information within the meaning of laws applicable to Canada. Such confidential commercial business information may include, but not be limited to, trade secrets and financial information. I agree to hold FDA and HC harmless for any injury caused by the sharing of this information.

Information to be shared:

> Documents and records related to a multipurpose audit/inspection conducted under the Pilot Multipurpose Audit Program.

Authorization is given to FDA and HC to share the above-mentioned information without deleting non-public information. By my signature, I warrant that I am authorized to provide this consent on behalf of *[insert name of manufacturer]* and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,

(Signature)
(Printed name)
(Title)
(Address)
(Telephone & Facsimile Numbers)

cc:

David Kalins
Office of Compliance
Center for Devices and Radiological Health
US Food and Drug Administration

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Ottawa ON Canada K1A 0K9

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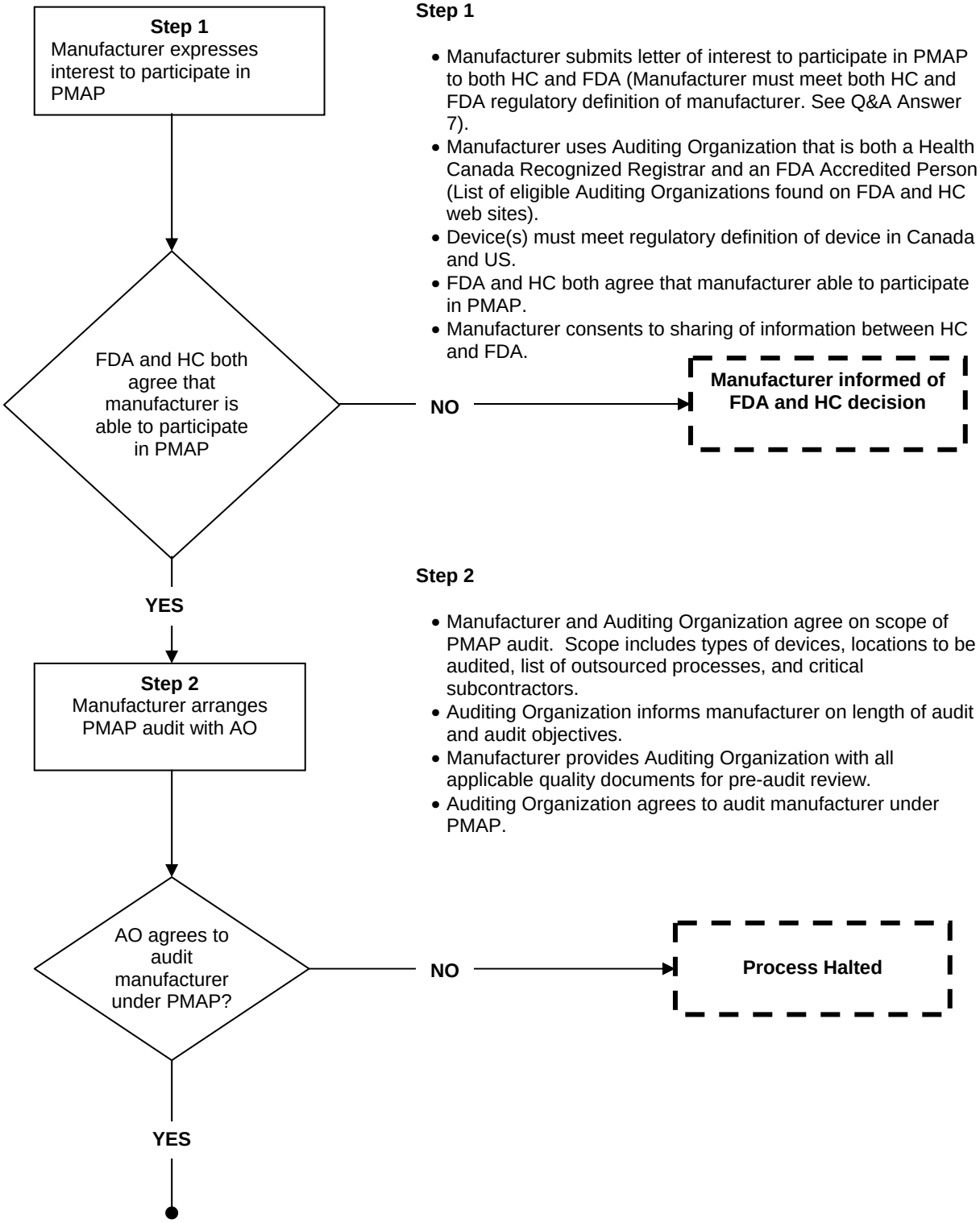
(613) 952-8250

Annex B
PMAP Multipurpose Audit Flowchart



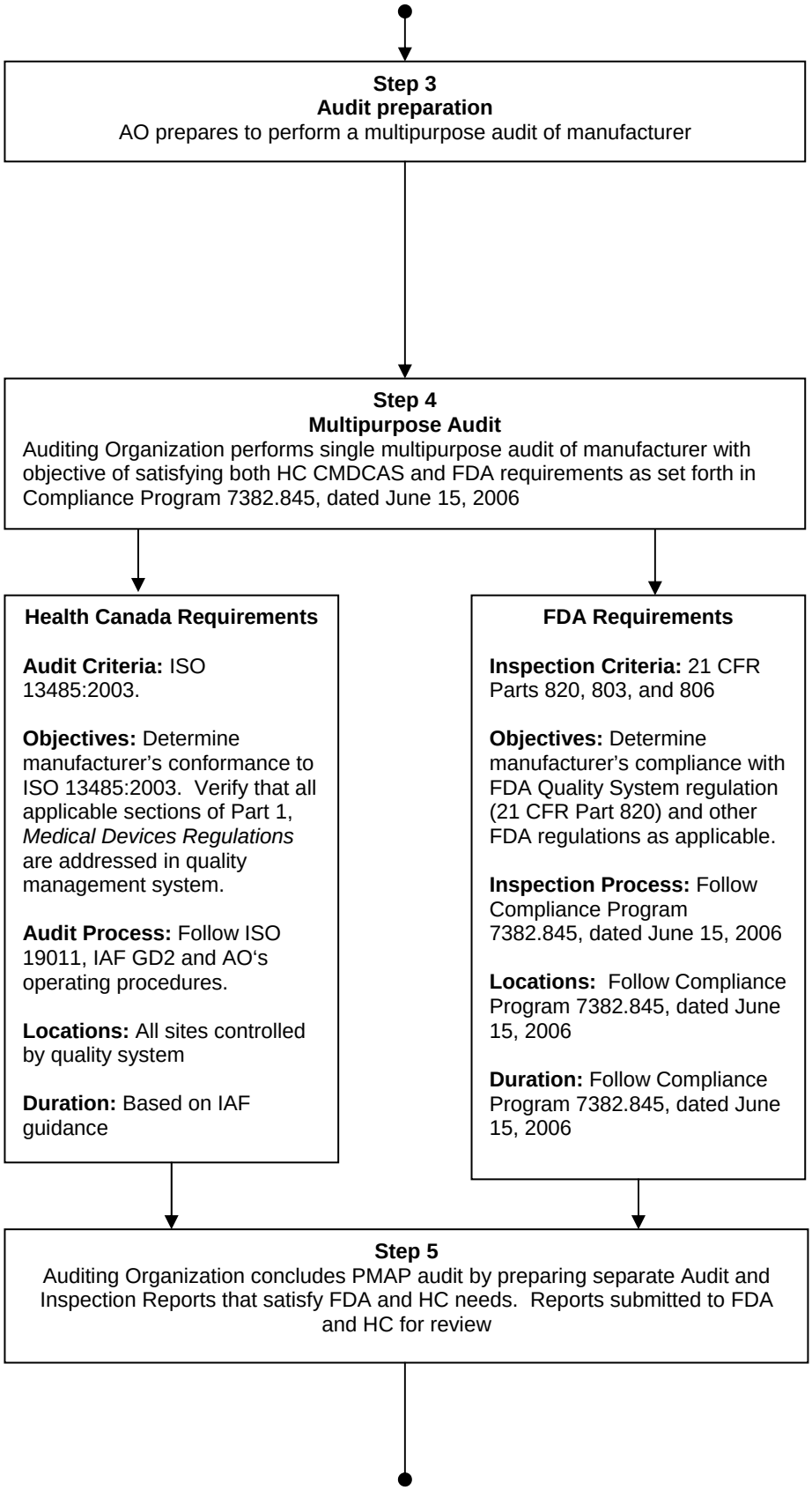
Step 1

- Manufacturer submits letter of interest to participate in PMAP to both HC and FDA (Manufacturer must meet both HC and FDA regulatory definition of manufacturer. See Q&A Answer 7).
- Manufacturer uses Auditing Organization that is both a Health Canada Recognized Registrar and an FDA Accredited Person (List of eligible Auditing Organizations found on FDA and HC web sites).
- Device(s) must meet regulatory definition of device in Canada and US.
- FDA and HC both agree that manufacturer able to participate in PMAP.
- Manufacturer consents to sharing of information between HC and FDA.

Step 2

- Manufacturer and Auditing Organization agree on scope of PMAP audit. Scope includes types of devices, locations to be audited, list of outsourced processes, and critical subcontractors.
- Auditing Organization informs manufacturer on length of audit and audit objectives.
- Manufacturer provides Auditing Organization with all applicable quality documents for pre-audit review.
- Auditing Organization agrees to audit manufacturer under PMAP.

Annex B
PMAP Multipurpose Audit Flowchart



Step 3

- Auditing Organization prepares FDA regulatory quality system inspection in accordance with FDA Accredited Person requirements as set forth in Compliance Program 7382.845, dated June 15, 2006.
- Auditing Organization prepares ISO 13485:2003 audit plan in accordance with ISO, accreditation body, and Health Canada audit requirements.

Step 4

- Auditing Organization audits against ISO 13485:2003 using procedures and criteria that meet intent of ISO Guide 62, ISO 19011 and Canadian Medical Devices Conformity Assessment System (CMDCAS).
- Auditing Organization inspects against FDA Quality System and other FDA regulatory inspection requirements. Follow Compliance Program 7382.845, dated June 15, 2006.
- Auditing Organization uses a single audit/inspection plan that encompasses both FDA and Health Canada requirements.

Step 5

- AO prepares Establishment Inspection Report (EIR) containing list of observations, narrative report, exhibits, and attachments.
- AO prepares audit report that includes findings of conformity or nonconformity.

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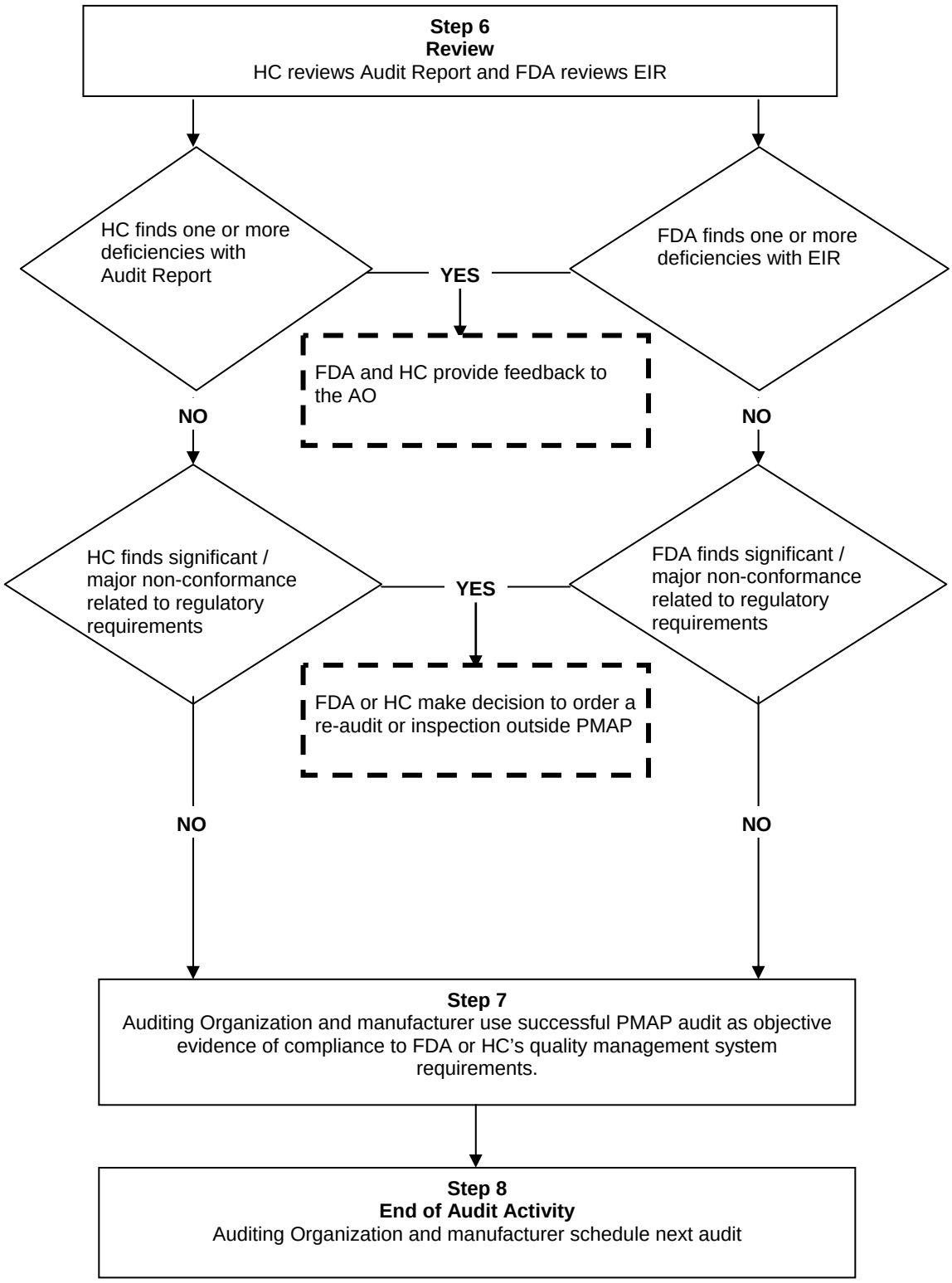
Step 6
Review
HC reviews Audit Report and FDA reviews EIR
HC finds one or more deficiencies with Audit Report
YES
FDA finds one or more deficiencies with EIR
FDA and HC provide feedback to the AO
NO
NO
HC finds significant / major non-conformance related to regulatory requirements
YES
FDA finds significant / major non-conformance related to regulatory requirements
FDA or HC make decision to order a re-audit or inspection outside PMAP
NO
NO
Step 7
Auditing Organization and manufacturer use successful PMAP audit as objective evidence of compliance to FDA or HC's quality management system requirements.
Step 8
End of Audit Activity
Auditing Organization and manufacturer schedule next audit