

MODEL COI POLICY

THIRD PARTY INSPECTION PROGRAM

The Third Party Recognition Board (TPRB) developed the attached model to assist potential Accredited Persons (APs) meet the Conflict of Interest (COI) requirements for APs who wish to participate in inspections, of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, that are required in section 510(h), or inspections of such establishments required to register pursuant to section 510(i) of the Federal Food, Drug and Cosmetic Act (the act).

A WORD ABOUT DOCUMENTATION

In our verification, we look for documentation that clearly shows what COI policies and procedures are **currently in place**. We feel documentation that is outdated, voluminous or unrelated to COI policy and procedure causes confusion and delays the review process. Any supporting documentation that is easy to find and understand facilitates the review process.

POLICIES AND PROCEDURES

In our verification, we look at the independence of the potential AP, its current COI policies, and its procedures to ensure current and future compliance with COI restrictions.

Independence - We look for evidence that makes clear that the potential AP:

- Is not owned, operated or controlled by a manufacturer, supplier, or vendor of articles regulated under the act.
- Is not financially affiliated with a manufacturer, supplier or vendor of these articles.
- Has the financial resources to act independently.

Written Organizational Policies - We look to see that the following statements are made:

- a. The AP applicant is not a Federal Government entity.
- b. The AP applicant is not owned, operated or controlled by a manufacturer, supplier or vendor of articles regulated under the act.
- c. The AP applicant has no organizational, material, or financial affiliation (including a consultative affiliation) with a manufacturer, supplier, or vendor of articles regulated under the act.
- d. The AP applicant is not engaged in the design, manufacture, promotion or sale of articles regulated under the act or the authorized representative of any of those parties.
- e. The AP applicant is impartial, does not charge fees contingent or based upon results from the AP inspections.
- f. The AP applicant holds all employees, including contractors, to the same COI standards.

Written Personnel Policies - We look to see that the following statements are made:

- a. Employees of the AP applicant involved in the inspection process do not engage in the design, manufacture, promotion or sales of articles regulated under the act.
- b. Employees of the AP applicant involved in the inspection process do not provide consulting services to any organization regulated under the act.

- c. Employees of the AP applicant involved in the inspection process, as well as their spouse and minor children, do not own stock or have any financial interest in any manufacturer, supplier, or vendor of articles regulated under the act.
- d. Employees of the AP applicant involved in the inspection process will not participate in an inspection of a firm for which they have performed prior assessments within the last 12 months.
- e. Employees of the AP applicant involved in the inspection process have not been employed by the firm being inspected within the last 12 months.

Written Procedures - We look to see that written procedures ensure that:

- a. There is a written COI declaration that there is no conflict of interest on the part of its regular or contract employees. That is, before each AP inspection those employees working on that inspection will declare in writing that they are free from any conflict of interest.
- b. There is no use of any officer, employee or contractor who has a financial conflict and the AP will annually make available to the public the extent to which the AP complies with its COI requirements.
- c. Employees or contractors with conflicts noted on the COI declaration will be disqualified from the review.
- d. Employees or contractors are aware that they must report any changes to their COI declarations to their supervisors as soon as the employee is aware of the changes.
- e. The AP applicant will handle any complaint promptly and will resolve all cases where conflicts are suspected or proven.
- f. COI declarations as well as any conflict resolution are made part of the official inspection file.
- g. COI training is provided to all employees, including contractors, to ensure compliance with AP applicants' written COI policies and procedures.

In an effort to demonstrate that the conflict of interest portion of your application need not be cumbersome or overly voluminous, we have included a model **COI document** that potential APs can use as a guide in developing their own operating policies and procedures.

MODEL COI POLICIES AND PROCEDURES – THIRD PARTY INSPECTION PROGRAM

Accredited Person Applicant (**APA**)

01 Independence Statement

APA is an independent company and legally constituted to conduct inspection work, that is neither owned, operated, nor controlled by a manufacturer, vendor or supplier of any articles regulated under the Federal Food, Drug, and Cosmetic Act (the act). It is a limited company wholly owned by its parent company APA International. Both APA and APA International were established in 1990 to perform conformity assessment activities. In addition APA also conducts general laboratory testing to internationally recognized standards. APA's total financial support is received from payment received for these activities.

Documentation to illustrate our independence includes the following:

- Copy of our brochure about services provided
- URL link to APA's internet homepage
- Annual report

02 Policy Statement

APA is committed to a high standard of excellence, integrity, and freedom from conflicts of interest. As a company, we affirm the following:

- a. APA is not a Federal Government entity.
- b. APA is not owned or controlled by a manufacturer, supplier or vendor of articles regulated under the act.
- c. APA has no organizational, material, or financial affiliation (including a consultative affiliation) with a manufacturer, supplier, or vendor of articles regulated under the act.
- d. APA is not engaged in the design, manufacture, promotion or sale of articles regulated under the act or the authorized representative of any of those parties.
- e. APA is impartial and does not charge fees contingent or based upon results from the AP inspections.
- f. APA holds all employees, including contractors, to the same COI standards.
- g. Employees of APA involved in the inspection process do not engage in the design, manufacture, promotion or sales of articles regulated under the act.
- h. Employees of APA involved in the inspection process do not provide consulting services to any organization regulated under the act.
- i. Employees of APA involved in the inspection process, as well as their spouse and minor children, do not own stock or have any financial interest in any manufacturer, supplier, or vendor of articles regulated under the act.
- j. Employees of APA involved in the inspection process will not participate in an inspection of a firm for which they have performed prior assessments within the last 12 months.
- k. Employees of APA involved in the inspection process have not been employed by the firm being inspected within the last 12 months.

03 Covered Employees

The following policies and procedures shall apply to all employees involved in the inspection process (regular, contract and supervisory personnel). Such persons shall be termed "covered

employees.” APA considers the Vice President for Medical Operations (Mary Johnson), the General Manager for System Monitoring (Don Browne), Team A (Donna Krauss), Team B (Samuel Brown) and anyone reporting to these supervisors (Joseph Cero, John Arnot, Beth Samuels, Jason Tompkins, Cathy Wilkins and Robert Munson) to be covered employees. (See Attachment D - APA Organization Chart for AP Activities) Since the President/CEO (Ralph Smith) doesn't participate in the day-to-day operation of the AP, he will not be considered a covered employee. However, he must ensure that he does not participate in any inspection or gives the appearance that he is in any way influencing the decisions made by covered employees.

04 Procedures to Ensure Compliance with Stated Policy

- Newly hired APA employees and all contract personnel will be asked to sign a pre-employment agreement that they understand and will comply with the APA's COI policies and procedures. This form entitled “Pre-employment Agreement to Ensure COI Compliance” is Standard Form (SF) 100A shown in attachment A.
- APA will ensure that employees or contract personnel are not assigned a task in which they have a financial interest. Specifically, the General Manager System Monitoring (GMSM), Mr. Broome, will ask all people involved in the review process to sign either the APA SF-100B - **COI Declaration for Individual Work Assignments Form for all APA Employees and Supervisors** (attachment B), or APA SF-100C - **COI Declaration for Individual Work Assignments for Contract Employees** (Attachment C) prior to the issuance of the assignment. If the employee or contractor is conflicted, then the GMSM will **disqualify** that person and **reassign** the task to another employee who is not conflicted. The Vice President of Medical Operations, Ms. Mary Johnson, will review the GMSM's COI declaration and President, Ralph J. Smith, will review Ms. Johnson's COI declaration to ensure no conflicts at the management level. Since Mr. Johnson is not a covered employee he can only review the Ms. Smith statement for conformance with COI policies, he cannot participate in any inspection or give the appearance he is in any way influencing the decisions made by covered employees.

*Note: All COI declaration statements contain a requirement for all people involved in the review process to **report any changes** to their current COI declaration as soon as they are known to the individual.*

- APA will **annually publish** on its webpage actions it has taken to ensure that it has followed the COI requirements of the AP program.
- If any employees or contract personnel fail to comply with the COI rules, the GMSM will **disqualify** and remove the employee or contract personnel from the assignment. Depending on the severity of the infraction, APA will proceed with disciplinary action up to and including termination of the employee; or termination of the contract if that is warranted by the facts. For this purpose the APA has set up an internal AP Review Board to handle any **COI complaints** related to the AP program as well as suspected or proven cases of COI. Complaints or COI matters that could affect human safety are of the highest priority and will be handled immediately. The board will meet promptly to address any other complaints or COI matters. Records of these meetings will include details on the issue(s) discussed, any actions taken to resolve the issue(s) and how the matter was concluded. These records will become part of the **official inspection file**.

- The **APA COI training plan** requires:
 - a. The GSM to reinforce the COI rules before each assignment and place a signed copy of each person's (AP employees and supervisors as well as contract personnel) COI determination in the **official inspection file**.
 - b. APA employees and contract personnel to receive an initial COI briefing prior to their signing the pre-employment form (SF- 100A) discussed above, and to receive yearly COI reminders of their APA's policies and procedures thereafter. The GSM will ask all employees to sign a form that they have read and understood the reminders and a copy of this form will be placed in the employee's personnel folder.

05 Contract Employees

The GSM will treat contract employees as they do APA employees. Specifically the APA will require contract employees to complete SF-100A "Pre-Employment Agreement to Ensure COI Compliance " (attachment A) as well as SF-100C "COI Declaration for Individual Work Assignments for Contract Employees" (Attachment C). The APA or the contractor will also provide training to contractors as noted in COI training plan noted above. All of these provisions will be noted in the actual Contract Agreement.

06 Fees

All fees collected by APA for services rendered in quality system reviews are not contingent on the positive or negative outcome of the review.

- The standard hourly rate will be used in estimating the client's bill.
- APA personnel (including any contract personnel used) are not remunerated according to the results of the audits they conduct. Salaries are based on the hourly rate in their employment agreements and the time spent on the assignment is monitored by GSM.
- APA personnel (including any contract personnel used) are not remunerated according to the number of audits they conduct during any given period.

ATTACHMENT A

**APA SF-100A
PRE - EMPLOYMENT AGREEMENT TO ENSURE COI COMPLIANCE
FOR ALL APA OR CONTRACT EMPLOYEES**

EMPLOYEE/CONTRACTOR NAME_____

DATE OF EMPLOYMENT_____

POLICY STATEMENT

All APA and contract employees are required to be free from any real or apparent Conflict of Interest (COI) as they perform their duties. Therefore, in performing my duties for APA, I agree that:

1. I do not engage in the design, manufacture, promotion or sales of articles regulated under the Federal Food, Drug and Cosmetic Act (the act).
2. I do not provide consulting services to any organization regulated under the act.
3. I, (as well as my spouse and minor children if applicable), do not own stock or have any financial interest in any manufacturer, supplier, or vendor of articles regulated under the act. Examples of firms regulated under the Act are listed on the following FDA website: <http://www.fda.gov/ohrms/dockets/yellow/yellotoc.htm> Please note that this list of firms is not all inclusive.
4. I understand that I must complete a COI declaration before conducting an inspection and that I must report any changes to my COI declarations to the General Manager for System Monitoring as they become known to me.
5. I will not participate in an inspection of a firm for which I have performed prior assessments within the last 12 months.
6. I will not inspect any firm that has employed me within the last 12 months.
7. I agree to act impartially and not give preferential treatment to any firm I am inspecting.
8. I will not solicit any gift or other item, nor accept any gift or other item, of monetary value from any person or entity seeking inspection.

I have read the above COI Compliance Statement as well as the APA's COI procedures, and will comply with these policies and procedures during my employment with APA. I understand that if I am assigned to work on any project in which I have a conflict of interest, or the appearance of a conflict of interest, that I will immediately notify the General Manager for System Monitoring and the project will be reassigned.

Signature_____

Date_____

ATTACHMENT B

**APA SF-100B
COI DECLARATION FOR INDIVIDUAL WORK ASSIGNMENTS
FOR ALL APA EMPLOYEES AND SUPERVISORS IN THE INSPECTION PROCESS**

EMPLOYEE'S FULL NAME _____

EMPLOYEE'S JOB TITLE _____

ASSIGNMENT _____

CLIENT FIRM _____

AS AN EMPLOYEE OF APA, I AGREE TO COMPLY WITH THE FOLLOWING COI RESTRICTIONS. I FURTHER UNDERSTAND THAT IF I FAIL TO COMPLY WITH THESE RESTRICTIONS, THE APA WILL REMOVE ME FROM THIS ASSIGNMENT, AND DEPENDING ON THE SEVERITY OF THE INFRACTION, PROCEED WITH DISCIPLINARY ACTION UP TO AND INCLUDING MY TERMINATION.

MY SIGNATURE AT THE BOTTOM OF THIS FORM INDICATES MY AGREEMENT WITH AND UNDERSTANDING OF THE FOLLOWING:

1. I am not currently engaged in the design, manufacture, promotion or sales of articles regulated under the Federal Food, Drug and Cosmetic Act (the act).
2. I do not provide consulting services to any organization regulated under the act.
3. Neither I nor my spouse or minor children own stock or have any financial interest in the client firm as well as any manufacturer, supplier, or vendor of articles regulated under the act.
4. I will report any changes to this COI declaration to the General Manager for System Monitoring as they become known to me.
5. I have not performed prior assessments for the client firm within the last 12 months.
6. I have not worked for the client firm within the last 12 months.
7. I will act impartially and not give preferential treatment to the client firm.

Employee's Signature _____

Date _____

ATTACHMENT C

APA SF-100C

**COI DECLARATION FOR INDIVIDUAL WORK ASSIGNMENTS
FOR CONTRACT PERSONNEL**

CONTRACTOR'S FULL NAME_____

CONTRACTOR'S COMPANY NAME_____

ASSIGNMENT_____

CLIENT FIRM_____

AS A CONTRACTOR FOR APA, I AGREE TO COMPLY WITH THE FOLLOWING COI RESTRICTIONS. I FURTHER UNDERSTAND THAT IF I FAIL TO COMPLY WITH THESE RESTRICTIONS, THE APA WILL REMOVE ME FROM THIS ASSIGNMENT, AND DEPENDING ON THE SEVERITY OF THE INFRACTION, TERMINATE ITS CONTRACTUAL AGREEMENT WITH MYSELF AND/OR MY FIRM.

MY SIGNATURE AT THE BOTTOM OF THIS FORM INDICATES MY AGREEMENT WITH AND UNDERSTANDING OF THE FOLLOWING:

1. I am not currently engaged in the design, manufacture, promotion or sale of articles regulated under the Federal Food, Drug and Cosmetic Act (the act).
2. I do not provide consulting services to any organization regulated under the act.
3. Neither I nor my spouse or minor children own stock or have any financial interest in the client firm as well as any manufacturer, supplier, or vendor of articles regulated under the act.
4. I will report any changes to my COI declaration to the General Manager for System Monitoring as they become known to me.
5. I have not performed prior assessments for the client firm within the last 12 months.
6. I have not worked for the client firm within the last 12 months.
7. I will act impartially and not give preferential treatment to the client firm.

Signature_____

Date_____

ATTACHMENT D

APA ORGANIZATION CHART FOR AP ACTIVITIES

