Escalation Procedure

Introduction

This document sets out the updated version of the Johnson & Johnson Escalation Procedure. Timely escalation in accordance with this policy is critical to ensure adequate and independent investigations by the appropriate departments. It is also critical in view of obligations the Company may have to disclose events reportable under this policy to government bodies. Failure to do so may expose the Company to potential legal sanctions.

The obligation to escalate under this policy is also valid for self-detected violations through financial controls, testing, monitoring, etc. Locally initiated investigations relating to any of these do not exonerate management of our companies to escalate reportable events under this policy.

As Operating Companies actively review, document, test and monitor their internal controls over compliance policies and programs, including those related to Sarbanes-Oxley, health care and anti-corruption compliance, government contracts and pricing, quality and EHS, potential or actual violations of Johnson & Johnson policies or law may, on occasion, be identified. Potential or actual violations of law may also be identified through the receipt of signed or anonymous letters or calls, employee hotline calls or reporting by employees directly to the Law Department, Internal Audit, line management or other corporate staff. These should be reportable events under this policy.

Other departments such as Worldwide Quality, EHS, IT Security and Corporate Security have in place escalation procedures that require notification to those offices when certain events occur. This policy is not intended to modify any of those processes. However, if there is an appearance, indication or evidence that those reportable events constitute or would constitute intentional breaches of the law or policies (including without limitation fraudulent documentation or intentional misrepresentations to government authorities), then such events must also be reported under this Escalation Procedure to the Law Department and the Vice President Corporate Internal Audit.

The Human Resources community is responsible for addressing allegations of harassment and discrimination. Those types of allegations are excluded from the scope of this Escalation Procedure unless related to any conditions mentioned as reportable hereunder. Also excluded are allegations that arise in the context of lawsuits brought by or against Johnson & Johnson or any of its operating companies unless related to any conditions mentioned as reportable hereunder.

If actual or potential non-compliances impact or may impact compliance with our government contracts or pricing obligations, these must be reported- regardless of severity or apparent financial impact - in accordance with the Government Contract and Pricing Supplement to the Escalation Procedure.
Escalation Procedure: When Corporate Internal Audit must be notified

It is critical that the Vice President, Corporate Internal Audit, be notified within three (3) business days (either verbally or in writing, including by e-mail), as soon as any of the following conditions are believed to exist, even though full details might not yet be available:

1. There is an actual or potential violation of the Johnson & Johnson Expense Reporting Policy or the Johnson & Johnson Global Travel and Entertainment policy and the amount in question exceeds USD 1,000 or involves a federal, state or local government employee.
2. An actual theft, fraud or defalcation occurs, irrespective whether covered by insurance or not, or there is a reasonable basis to suspect that a theft, fraud or defalcation has occurred, that in either case may exceed USD 1,000.
3. There is an actual or potential violation of any of the following policies that could result in an employee, including a temporary employee, being terminated or suspended: the Johnson & Johnson Financial Reporting Procedures; the Johnson & Johnson Government Contract Compliance Guidelines; the Johnson & Johnson Health Care Compliance Guidance Policies; the Johnson & Johnson International Health Care Business Integrity Guide; the Johnson & Johnson Code of Business Conduct or the Code of Business Conduct and Ethics for members of the Board of Directors and Executive officers. If any of these violations or potential violations occurs as mentioned hereunder in section 3, the threshold of USD 1,000 as referred to under Sections 1 and 2 does not apply.
4. There is an actual or potential violation of law (including instances when any Johnson & Johnson company is informed that a government investigation has been started or is ongoing) by a Johnson & Johnson company, employee or agent that could result in a fine, monetary penalty or administrative sanction (regardless of the amount), criminal prosecution of the Company or its employees, or other legal or regulatory consequence. Actual or potential violations of the FCPA or any other anti-corruption law must ALWAYS be reported.
5. A third party has or potentially has violated a critical contractual clause when violation of such a clause could result in a significant financial loss to Johnson & Johnson.
6. Any other situations that potentially involve a significant loss of Company funds.
7. Any allegations of misconduct by a management board member.
8. There is a potentially substantial risk to the reputation of Johnson & Johnson or one of its business units that is not already required to be reported under Worldwide Quality, Worldwide Security or EHS procedures.

Investigative work should not be started before this notification, except as necessary to verify whether the allegation meets the criteria above. In the event law enforcement authorities issue search warrants or take an employee in custody, Worldwide Security and the Law Department should both be notified to coordinate the appropriate response.

Examples:

Examples of issues that should be reported to CIA include, but are not limited to, the following:

- Any allegation that an employee falsified or altered a document or record required to be
kept under applicable government laws and regulations and/or J&J policies

- Any allegation of employee misconduct during the course of a government inquiry or investigation, such as a knowing or intentional misrepresentation to a government official or investigator, or inappropriate destruction of documents
- Fraudulent (e.g., fake or altered) receipts were submitted to an expense report if the aggregate amount involved exceeds USD 1,000. However, if the aggregate amount does not exceed USD 1,000, reporting to CIA is still mandatory when there is a suspicion or indication that it could relate to a violation of FCPA or other anti–corruption laws.
- Allegations of improper payments to government officials or other breaches of the FCPA or anti–corruption laws
- Allegations of payments to health care professionals that are not in accordance with Johnson & Johnson policies (irrespective of the amount involved)
- Payments were made or other items of value were given to a third party (e.g., vendor, customer) that are inappropriate because prohibited by a Johnson & Johnson policy or because payment was not in exchange for value received from the third party
- A conflict of interest between an employee and a vendor or customer is alleged and was not previously investigated, approved and communicated in accordance with the Code of Business Conduct
- Financial statements that have been falsified as a result of entries that appear to be deliberately erroneous
- Allegations of non-compliance with antitrust or competition laws
- Allegations regarding misappropriation of confidential information or trade secrets
- Allegations regarding significant breaches of privacy requirements that potentially may trigger fines or notifications to government and/or the general public
- Company assets were given to Johnson & Johnson employees or any other person for non-business reasons, e.g., an employee gives a vendor USD 500 in gift checks
- Information submitted to the government (verbally or in writing) was inaccurate, including but not limited to, pricing, government calculations, business practices, certifications, disclosures or responses to audits/inquiries
- A failure to abide by or meet the requirements of a government contract or pricing program

Notification pursuant to the escalation policy is necessary because of the heightened emphasis on internal controls to assure compliance with laws and regulations, the serious potential legal and reputational consequences of significant compliance failures and the need to analyze and remediate control issues, as appropriate. In addition, notification with respect to substantial risks to the reputation of Johnson & Johnson or one of its business units or risks of substantial business interruption is necessary because either one can have serious financial consequences.

It is important that Johnson & Johnson have a central repository where all such matters can be gathered and monitored. In Johnson & Johnson, the Vice President, Corporate Internal Audit, will serve as the focal point for receiving reports, will monitor timely investigation and resolution of these potential violations, and will report on such matters to senior management and, where appropriate, the Audit Committee.

**When Corporate Internal Audit should not be notified**
Examples of issues that should not be reported to Corporate Internal Audit include, but are not limited to, the following:

- An employee fails to attach receipts for items over USD 25.00, but it has been demonstrated that the underlying transactions do not violate any Johnson & Johnson policies. This should be addressed at the Operating Company level.
- Potential violations that involve harassment, physical altercations, discrimination and similar violations. These matters should be addressed by the HR organization with Law Department involvement as necessary.
- Potential violations of Johnson & Johnson policies that would clearly not result in an employee being terminated or suspended. These matters should be addressed at the Operating Company level.

Each Operating Company must maintain a record of the matters not required to be reported to Corporate Internal Audit. These records must be maintained in a single repository at the Operating Company, and must include the issue, the investigation findings, and the resolution, including any employee sanctions. Corporate Internal Audit may from time to time review such records during the audit process. Matters escalated according to this procedure to Corporate Internal Audit do not need to be recorded in the local records.

**What must be included in Corporate Internal Audit Notification**

The following information must be included in the required notification, if available. In some cases, notification will be made through a call to the hotline. In those cases, reporters should call with whatever information they have, rather than investigate matters themselves.

- A preliminary description of the event(s) that occurred, based on the details available at the time of the notification
- When the event(s) occurred
- How the issue was originally detected
- The potential dollar quantification of the issue
- Name and title of person(s) having relevant information related to the occurrence
- Root cause preliminary assessment, e.g., inadequate controls
- Steps that will be planned in the investigation, including the name of the lead investigator proposed

**Conducting the Investigation**

All cases will be handled consistent with the Triage Committee process. Depending on the facts and circumstances of any issues reported to Corporate Internal Audit, the Triage Committee will review and determine which corporate organization will take the lead in conducting the investigation. The Triage Committee consists of the Chief Compliance Officer; the Vice President, Corporate Internal Audit; representatives from the Law Department; and, on an ad hoc basis, representatives from Worldwide Security and Human Resources.

Once a matter is escalated to Corporate Internal Audit, the Operating Company and its management concerned should not conduct any investigative steps, and should not contact
anyone else about the matter unless advised to do so by Corporate Internal Audit, the Law Department, or Health Care Compliance & Privacy.

With respect to those issues reported to it that do not require Triage Committee consideration, Corporate Internal Audit will determine whether it will conduct the investigation itself or delegate responsibility for the investigation to the Operating Company or a third party. In addition, Corporate Internal Audit will consult with the Law Department in appropriate circumstances. Operating Companies to whom investigative responsibility has been delegated are responsible for timely investigation, adequate documentation, and resolution. Corporate Internal Audit and/or the Law Department may assist or advise the Operating Company to facilitate the investigation. Final results of investigations conducted by Operating Companies must be promptly reported to Corporate Internal Audit and, where appropriate, input into the EthicsPoint case management system. Operating Companies are also responsible for inputting corrective actions into the EDGE database (which is used to track corrective actions). Corporate Internal Audit and the Law Department aim to ensure that all investigative and review standards are applied consistently and fairly to all employees.

Questions

If you have any questions, please contact John Crisan or Gary Fair.

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Gary Fair
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Corporate Internal Audit
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APPENDIX

U.S. Government Contract and Pricing Supplement to Escalation Procedure

Distribution

This Supplement should be read by all members of a Johnson & Johnson organization who have direct or indirect responsibility for selling to or contracting with the U.S. Federal Government or whose products may be reimbursed by U.S. Federal government entities.

Background

Johnson & Johnson employees are required to comply with all applicable federal, state, and local laws, regulations, contract terms and conditions, and related Johnson & Johnson policies governing our business operation, and to report any prohibited or unlawful acts of which they are aware. The Johnson & Johnson Operating Companies are each responsible for carefully monitoring compliance, and there is an established escalation procedure to ensure appropriate investigation and resolution of issues as they arise.

To this end, the world-wide Escalation Procedure establishes the protocol for reporting of any potentially serious violation of law that could result in a significant fine or other substantial legal consequences. It requires that the Vice President, Corporate Internal Audit (CIA), or their designee, be notified within three (3) business days either verbally or in writing, including by e-mail, if certain violations are believed to exist. Notice to CIA is required in this timeframe even when full details, including validation or financial impact, are not yet available. This is necessary to assure that the outcome of any investigation or determination of compliance is not compromised by the manner in which such matters are reviewed. Personnel are permitted to inform their management or a law department representative of potential concerns prior to notifying CIA, so long as the matter is appropriately reported to CIA within three (3) business days of the matter initially being identified. Stated differently, the three day clock starts to run when the matter is initially raised, not after it has been reported to an individual’s supervisor. Corporate Internal Audit acts as a central repository for all reported matters and monitors the timely investigation and resolution of these potential violations. Depending on the facts and circumstances of any issues reported to Corporate Internal Audit, the Triage Committee will convene and determine which organization (HCC/GCC/Law Department/CIA or Operating Company) will take the lead in conducting the investigation.

GCC Supplement to the Escalation Procedure for Federal Contractors

The purpose of this memo is to remind individuals that since December 2008, Johnson & Johnson affiliates who contract with the United States Federal Government (“Federal Government”) have been subject to an additional requirement known as the Mandatory Disclosure Rule. This rule requires companies that contract with or sell to the Federal Government to timely disclose “credible evidence” to the government of certain violations of criminal law (involving fraud, conflict of interest, bribery or gratuity violations with government employees or officials), violations of the civil False Claims Act,
or significant overpayments in connection with the award, performance, or closeout of the
government contract. Separately, under FAR 52.222-50 (Ending Trafficking in Persons) (March 2015)
(the “Human Trafficking Rule”), companies that contract with or sell to the Federal Government are also
required to immediately disclose “credible information” to the government relating to allegations of
trafficking in persons by the Company, any employee, subcontractor, subcontractor employee or agent.
Failure to make a timely disclosure subjects the Johnson & Johnson Company, as well as any principals
of the Company that had such knowledge and failed to act, to suspension or debarment from
Government contracting. The Company also may be subjected to additional fines and penalties. The
Mandatory Disclosure rule and Human Trafficking Rules are two of several that have been
implemented recently to provide the Federal Government with more information about potential
contractors towards the goal of assuring that the Government is spending taxpayers’ money responsibly.

Adherence with our obligations under the Mandatory Disclosure Rule and the Human Trafficking
Rule, as well as other transparency obligations, is facilitated through the GCC Supplement to the
Escalation Procedure. The GCC Supplement adds two requirements to the Escalation Procedure: (1) it
identifies additional types of potentially non-compliant activity that must be reported, and (2) it
establishes a different threshold for reporting situations that have the potential to impact GCC
compliance. These additional escalation obligations are designed to ensure that all circumstances that
may equate to a non-compliance with a Government contracting or pricing obligation are fully reviewed
and the proper disposition is made and documented, even for those situations that are determined not to
warrant disclosure under the Mandatory Disclosure Rule. Further, these escalation procedures are
designed to allow for an immediate disclosure of “credible information” concerning an alleged violation
of the Human Trafficking Rule. Your cooperation with this procedure further enables our collective
compliance.

Reports

Johnson & Johnson has many channels available to receive reports of possible violations, including: line
management, compliance professionals throughout the organization, the General Counsel and members
of the Johnson & Johnson Law Department, the Compliance “hotline,” and Corporate Internal Audit.
Any of the above who receive reports covered by this policy is required to timely notify Corporate
Internal Audit or so that the matter can be tracked and a thorough review conducted.

When Corporate Internal Audit must be notified

The Vice President, Corporate Internal Audit (“CIA”) must be notified (1) as soon as, and in no event
later than three (3) business days after, any of certain conditions are believed to exist, even though full
details may not yet be available and the impact to Government contract compliance is not yet
determined; and (2) immediately of any credible information suggesting that a violation of the Human
Trafficking Rule has occurred. This notification can take place orally or in writing, including via e-
mail. It is permissible to contact and discuss the relevant circumstances with a designated subject
matter expert in the Law Department or a designated Compliance contact prior to notifying CIA, so
long as the notice to CIA occurs within the required three (3) business days. With respect to reports
concerning the Human Trafficking Rule, it is permissible to contact and discuss the relevant circumstances with a designated subject matter expert in the Law Department or a designated Compliance contact concurrent to reporting the information to CIA. The designated legal subject matter experts for government contract and pricing matters are Stephanie Gilson, Jessica Empestan, and Perry Knight in the Regulatory Law Group. An individual is permitted to discuss a potential non-compliance with their supervisor prior to reporting the matter to CIA or the Law Department, so long as the other requirements stated here are met. In this circumstance, the supervisor shares responsibility for assuring that the potential non-compliance is properly and timely escalated. Except as provided for here, information about a potential non-compliance should not be shared with anyone other than CIA or the appropriate subject matter experts in the Law Department, nor should any investigative or other work be performed on the issue until further direction is received from CIA or the Law Department.

**Triggering Events**

While it is not possible to list here each and every possible noncompliance relevant to government contracting and pricing that must be reported, we have endeavored to identify certain categories and specific examples of types of possible violations that may be encountered and that are subject to the Escalation Procedure. Please note that potential violations must be reported whether they involve the Company, its officers, directors, managers, employees, agents, vendors, subcontractors, partners or others with whom it does business. While the Escalation Procedure generally requires the reporter to make a reasonable determination of severity in order to identify those issues which should be reported to CIA versus handled internally, all actual or potential noncompliances must be reported—regardless of severity or apparent financial impact—if it might impact compliance with our government contracts or pricing obligations. Thus, it is anticipated that in some, if not many instances, a simple mistake, a human error, or an immaterial non-compliance with a commercial contract or practice will be escalated because of its potential impact on government compliance. Consider also that the timely identification and reporting of even these situations with immaterial impact enables Johnson & Johnson to demonstrate that it has an effective compliance program in place and to rectify problems prior to there being a material financial impact. Notwithstanding the guidelines above, any credible information concerning a potential violation of the Human Trafficking Rule must be immediately reported to CIA.

Specifically, individuals must timely report to CIA any information related to:

1. An actual or potential violation of the Johnson & Johnson Expense Reporting Policy involving a federal, state, or local government employee.
2. An actual theft, fraud, or defalcation occurs or there is a reasonable basis to suspect that a theft, fraud or defalcation has occurred that, in either case, may relate to a government contract.
4. A false statement was made to the government, whether orally or in writing, or there was a failure to timely disclose required information to the government.
5. A failure to abide by the terms of a government contract or pricing program, whether it results from failure to timely and accurately disclose pricing, failure to charge the agreed upon price or pay appropriate rebates, failure to perform required processes or tests, failure to deliver products that conform to contract requirements, or failure to adhere to country of origin requirements.
6. A third party performing services relating to government pricing or contracting compliance has or potentially has violated a critical contractual clause, including an actual or potential violation of the Human Trafficking Rule.

Accordingly, items that should be reported to CIA include, but are not limited to, the following. Please note that this list is not exhaustive, and when in doubt, report the information so that the appropriate experts can perform a thorough review.

- An error is discovered in a previously submitted government pricing calculation. Some causes for this may include, but are not limited to, an error in the formula used, use of incomplete data, or miscategorization of a payment, inaccurate or incomplete commercial sales data
- Country of manufacture for a product was changed resulting in a different Country of Origin, without disclosure to affected government purchasers (i.e. Trade Agreements Act/Buy American Act violations)
- Violations of the Price Reductions clause in FSS contracts, either due to failure to timely disclose, incomplete disclosure, or failure to adjust price
- Defective Pricing resulting from failure to adequately disclose commercial sales practices
- Invoices issued to government payors reflecting an incorrect payment amount
- System issues that have broad implications & government transactions are processed in the same system
- Misstatements made in connection with contract negotiations with or proposal submissions to the government
- Falsification or unauthorized destruction of Company books & records
- Consulting agreements with government employees or officials entered into without written evidence of permission from designated Government ethics representatives.
- Instances of gratuities (including meals) given to Government employees or officials in excess of permissible limits or circumstances
- Instances of grants made to Government or Government-affiliated entities without written evidence of internal and government approvals
- Credible information suggesting that a Company has engaged in violation of the Human Trafficking Policy, such as charging employee’s recruitment fees, or failing to provide employment contracts or work documents where required by law

If you have any questions related to the Mandatory Disclosure Rule, please contact Stephanie Gilson, Jessica Empestan, Perry Knight, as members of the Johnson & Johnson Law Department. If you have any questions related to the Escalation Procedure, please contact John Crisan or Gary Fair.
## Document Approvals

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