City of Houston OIG Releases Report on HFSC Incident

March 25, 2016

FOR IMMEDIATE RELEASE

The City of Houston's Office of Inspector General (OIG) has completed an investigation into three incidents at the Houston Forensic Science Center (HFSC) and made recommendations to avoid similar situations in the future. HFSC requested the OIG investigation in February 2016 immediately after an anonymous complaint was filed with the Texas Forensic Science Commission (TFSC.)

The OIG investigated three separate incidents in HFSC's Toxicology Section, focusing on the mistakes, but more narrowly on how the errors were reported to the Center's Quality Division.

The three separate incidents involved analysts accidentally pushing the wrong button on a new piece of lab equipment, contaminating evidence. In all three instances, the analysts had a second, uncontaminated vial of blood to test and the end result was unaffected. However, because the incident reoccurred, HFSC opened its own internal review in October when the Quality Division was informed and has since updated its procedures to ensure the same mistake does not happen.

"HFSC appreciates the careful and considered investigation by the OIG and looks forward to cooperating with TFSC to further look into the incidents and ensure the mistakes do not reoccur," said Dr. Peter Stout, the Center's COO and vice president.

"HFSC is aware the incidents investigated by the OIG and TFSC could have and should have been avoided. HFSC has conducted its own internal review to determine what

went wrong and has changed policies and procedures to avoid similar incidents going forward," Stout said.

The incidents investigated by the OIG and TFSC involved the incorrect use of a new instrument, a Hamilton 600 pipette, that allows analysts to remove and inject substances from one container into another. The instrument has two buttons, one on top of the other. One button draws a liquid into the pipette tip, while the second ejects the substance. HFSC began using the instrument in April 2015. About a month later, on May 28, 2015, the first error occurred in the use of the instrument. In October the mistake was made two more times.

The October incidents were immediately reported to the Center's Quality Division, and an internal investigation began. At that point, the Quality Division was also informed of the May incident, and it too was included in the investigation. By November 18, the Quality Division's investigation was completed and changes were implemented to avoid this error from being repeated.

Analysts are now required to remove blood from the evidence vial and place it into a separate labeled container. This is then used for further testing, preserving the original evidence. The Hamilton 600 never touches the original evidence container.

The anonymous complaint to the TFSC stated the first incident in May should have been investigated internally. But the Quality Division had not been informed until October when the two additional errors occurred. As a result, the OIG has recommended HFSC update its reporting procedures to ensure staff understand everyone is responsible for guaranteeing the integrity of HFSC's science and immediately reporting nonconformities to the Quality Division. HFSC is currently updating its manual.

"HFSC is constantly working to improve the quality and efficiency of its scientific analysis," said Dr. Daniel Garner, the Center's CEO and president. "That said, we do rely on people in our laboratories, and on occasions mistakes will be made. It is our job to immediately address such incidents and put processes and procedures in place to avoid them going forward."

HFSC is a local government corporation that provides forensic services to the City of Houston and other local agencies. HFSC is overseen by a Board of Directors appointed by the Mayor of Houston and confirmed by the Houston City Council. Its management structure is designed to be responsive to a 2009 recommendation by the National Academy of Sciences that called for crime laboratories to be independent of law enforcement and prosecutorial branches of government.

HFSC currently operates in nine forensic disciplines.

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TO: HOUSTON FORENSIC SCIENCE CENTER

Recd by TPA
3-23-16
12:45 pm

DATE: March 23, 2016

SUBJECT: **Houston Forensic Science Center**
OIG#1111600030
(Complaint to TFSC)

CONFIDENTIAL ATTORNEY – CLIENT COMMUNICATION/WORK PRODUCT

TITLES ONLY

OFFICE OF INSPECTOR GENERAL REPORT

This Office of Inspector General (OIG) Report responds to the Houston Forensic Science Center (HFSC) referral and an anonymous complaint filed with the Texas Forensic Science Commission (TFSC) that reads in pertinent part as follows:

> On 5/28/15 Analyst #1 using a Hamilton Microlab 600 pipette dispensed internal standard directly into a blood vial (not the headspace vial, the actual blood/vial tube). This lead to contamination of one of the blood vials collected from the defendant. The second vial was ultimately tested apparently without notification to the defendant. I have a reason to believe management was notified at the time of this event. However a corrective action was not issued for the incident until November 16, 2015. It is important to note that this CAPA was apparently only issued after Analyst #1 and another analyst, Analyst #2, did the exact same thing in October. These separate incidents of dispensing internal standard into the blood vial occurred on October 28 and 29, 2015. Had a corrective action been issued in a timely fashion, perhaps in June, the other two incidents might not have occurred....As the Commission is fully aware this is not the first time HFSC/HPD Crime Lab has failed to timely issue a CAPA. In January 2015, the Texas Forensic Science Commission issued a finding of professional negligence for failure to issue timely CAPAs.

For easy reference, OIG has attached the relevant section of the Quality Manual on correct handling of "nonconformities" as Exhibit A.

CHRONOLOGY OF FACT FINDINGS

(All dates are "on or about" dates based on witness interviews and documentation.)

August 25, 2014 – HFSC President and CEO appointed "Quality Director" to the position of HFSC Quality Assurance Director and had her report directly to him rather than to Forensic Analysis Division Director.

April 2015 - HFSC toxicologists began using the Hamilton 600 instrument to automatically perform aliquots (portioning) during blood specimen testing. Prior to this, HFSC performed aliquots manually.

Thursday May 28, 2015 –Using the Hamilton 600, Analyst #1 mistakenly injected internal standard into the blood specimen of defendant, (2015-05495). Analyst #1 noted on the assignment report sheet: *"1 vial" n-propanol pipetted into item 1.1 during second aliquot.*" Per Analyst #1, she immediately notified Acting Lab Manager, a consultant, about the error. Acting Lab Manager instructed her to open the second vial and conduct the test from that sample because that would be her home lab procedure. Analyst #1 did not immediately follow this directive. Supervisor was on vacation. Based on her experience, Acting Lab Manager thought the error warranted a CAPA, but didn't know "if I had the authority to do that or not."

Monday June 1, 2015 - Per Supervisor, she "probably" heard about Analyst #1's error during informal discussion by lab personnel upon her return from vacation. Per Supervisor, "I was made a supervisor in January 2015 so I was fairly new. I probably did not think to [consider a CAPA] and that was the first incident we had about injecting into a tube so I probably did not think to write a CAPA. Now that I know more about CAPAs and incident reports and all that…but back then…I did not know."

June 4, 2015 – At a weekly staff meeting including Vice President and COO, Senior Forensic Analyst, Forensic Analyst-Drugs, Specialist, Senior Analyst, Supervisor, and Specialist, Analyst #1 raised for discussion her 5/28/15 error and the process for notifying the District Attorney's office. The group decided Analyst #1 would prepare a draft and request assistance.

June 9, 2015 –Analyst #1 emailed Vice President and COO and Counsel and copied Forensic Analysis Division Director and Supervisor for assistance with her proposed notification memo to the Assistant District Attorney (ADA) about the May case (2015-05495) indicating that the second blood tube had to be opened for testing.

June 15, 2015 – Toxicology Manager began employment as HFSC Lab Section Manager.

June 26, 2015 – Supervisor emailed Analyst #1 requesting the case report for 2015-05495 stating: "It looks like you already analyzed the sample back on 5/28/15 but did not write the report." Supervisor incorrectly assumed Analyst #1 had opened and tested the second vial on 5/28/15 as Acting Lab Manager had instructed her to do.

July 8, 2015 – Following the instruction of Toxicology Manager and Supervisor, Analyst #1 opened and tested the second vial of blood from defendant (2015-05495).

July 14, 2015 – Analyst emailed ADA and copied Forensic Analysis Division Director indicating she had opened the second tube and tested using only "a small portion of the tube" and "leaving enough for secondary testing."

July 28, 2015 – As requested on 6/26/16, Analyst #1 wrote the Alcohol Analysis Report for the May case (2015-05495-1) stating: "[d]uring sample preparation, the specimen became unsuitable for analysis." Supervisor reviewed it the same day.

October 28, 2015 – Analyst #2 mistakenly injected internal standard into the blood specimen of defendant (2015-13730-1). Per Analyst #2, she immediately reported it to her supervisor, who in turn reported it to Toxicology Manager.

October 29, 2015 – Analyst #1 mistakenly injected internal standard into the blood specimen of defendant (2015-09198-2). Per Analyst #1, "That's when we had a manager so we talked about exactly how we wanted to document it."

October 29, 2015 –Toxicology Section Standard Operating Procedure entitled "Analysis of Alcohol and Other Volatiles by Headspace GC/FID" revised and issued.

October 30, 2015 – Toxicology meeting held with agenda item: "Aliquoting blood specimens into separate tubes for alcohol analysis – A small portion of the tube will be put in a separate container every time and discarded as soon as the vial is prepared."

November 3, 2015 – Toxicology Manager and Supervisor submitted draft of incident tracking report to Quality Division (Quality Director).

November 5, 2015 – Per Quality Director, she met with Toxicology and learned for the first time about the identical May 2015 error.

November 9, 2015 – Toxicology Manager and Supervisor redrafted the initial incident report into a CAPA report and presented it to Quality Division, Quality Director. Quality Director approved the final version that same date and Forensic Analyst-Alcohol and Forensic Analyst-Alcohol electronically signed off that day as well.

November 10, 2015 – Supervisor and Toxicology Manager signed off electronically on final version of the CAPA.

November 10, 2015 – Analyst #1 wrote the alcohol-analysis report on case #2015-09198-2. Supervisor reviewed it the same day.

November 16, 2015 – Analyst #2 wrote the alcohol-analysis report for case #2015-13730-1. Supervisor reviewed it the same day.

November 16, 2015 – Forensic Analyst Division Director electronically signed off on final version of CAPA.

November 18, 2015 – Quality Director electronically signed off on final version of CAPA. Quality Director decided not to submit CAPA to the TFSC because she felt the three errors did not rise to the level of "professional negligence" required for required self-disclosure to TFSC.

February 2, 2016 – Anonymous complaint filed with the Texas Forensic Science Commission.

February 3, 2016 – HFC requested OIG investigation.

February 15, 2016 – Per Forensic Analysis Division Director, HFSC CAPA/Incident Documentation Flow Chart discussed and re-introduced to management staff during meeting.

I. NOTIFICATION TO QUALITY MANAGEMENT

OIG first considered whether HFSC correctly handled notification of the May 2015 error. Section 4.9.1 of the Quality Manual (See Exhibit A) provides:

> Issues regarding the quality of technical services provided by the Center *are brought* to the attention of the appropriate section manager and the Quality Director, or their designee(s). (emphasis added)

Buried in the later portion of 4.9.1 under the classification levels is the sentence:

> The manager or technical leader is responsible for investigating and reporting the occurrence to the Quality Division in a timely fashion.

While the Section is poorly written not to combine these sentences and uses the word occurrence instead of nonconformity used elsewhere, OIG reads the Quality Manual to require all management or technical leaders on notice of the error to report to Quality management or assure that it has been reported, including section managers, managers, and up the chain.

A. FACTS

On 5/28/15, Analyst #1 mistakenly injected internal standard into one of two vials containing the blood specimens from defendant (2015-05495-1). Analyst #1's immediate supervisor was on vacation, but Analyst #1 considered the contractor on site to be her acting supervisor. Analyst #1 notified Acting Lab Manager immediately. Acting Lab Manager reported that she acted as a "consultant" to HFSC, not as an acting laboratory manager. She advised Analyst #1 that her lab procedure would be to use the second blood vial, but that she had no information on HFSC protocols. Acting Lab Manager did not report the error to Quality Management or anyone else at HFSC.

HFSC Supervisor returned from vacation the following Monday (6/1/15). She admitted she heard about the error but failed to report to Quality management. Supervisor felt the error had to be documented and believed that occurred when Analyst #1 noted on the assignment report sheet: *"1 vial" n-propanol pipetted into item 1.1 during second aliquot,*" and noted in her Alcohol Analysis Report that "[d]uring sample preparation, the specimen became unsuitable for

analysis." Supervisor explained that she had only been in her supervisory capacity for approximately five months at the time so she "probably did not think to write a CAPA."

By emails dated 6/9/15 and 7/14/15 respectively, Analyst #1also notified Vice President and COO and the Forensic Analysis Division Director of the 5/28/15 error when she asked about proper notification to the customer. Initially, Forensic Analysis Division Director reported that at the time of the May error she was still involved with Quality management. Neither management employee thought to ask if anyone had notified Quality management. Initially, Forensic Analysis Division Director stated that she did not remember being notified until the October repeats of the same error. First she stated: "I would think Supervisor brought in Quality to let them know…that this occurred." However, she admitted:

> Looking back we should have made it an incident right from the get go. Obviously a sample is contaminated. Yeah…let me just say it fell through the cracks.

When shown the emails where Analyst #1 notified her, Forensic Analysis Division Director appeared to separate herself from the Quality Management process by stating:

Did this in effect serve you notice of the 5/28/15 incident?
"This would have been one of the incident…or anomaly…an issue with testing. There's an event that occurred…so she's notifying me and Supervisor and several individuals that this happened in my testing and this is what I am going to do….

Did you ever talk with Quality Director about this at the time?
"I don't recall speaking to her about this incident."

But you being aware of it makes Quality Management aware of it. Is that correct?
"The way it works is they notify managers, the Quality Director and as appropriate the division…to prompt a corrective action."

So Quality is aware of it at this time?
I don't know if Analyst #1 made Quality aware of it. She might not have. I don't know if she…

Aren't you part of Quality at this time?
"No. The Quality division is separate from the Forensic Analysis Division. We are two separate divisions."

So you are not involved in Quality Management at the time this email came out?
"The only way I am involved…yes…sometimes they do notify me initially but other times I am notified toward the latter part when they are working through Quality with their incidents.

Quality Director, though admittedly in hindsight, reported:

> Had this occurrence been brought to Quality division's attention in May…forgive me for looking backwards…I don't believe it would have been handled any differently in May than it was in October or early November. From a Quality perspective we didn't handle this as a corrective action because it happened three times; we handled it as a corrective action because that is what we would have done the first time."
>
> **Had you been aware of it?**
> "Right. The reason I would have been inclined to report it that way was because it impacted the evidence. I just want to make it clear that I don't agree with what you say that 'because it happened three times.' It would have been handled that way the first time."

B. FINDINGS

OIG sustains the concern that none of the individuals in the operational chain of command on notice of the error notified the Quality Director of the May 2015 error, resulting in an improper reporting delay from May to November. Because of the totality of the circumstances including the large amount of contemporaneous discussion about the May 2015 error within the operational chain, OIG does not find any malfeasance in the error.

C. RECOMMENDATIONS

Because the Quality Manual assumes all are responsible to report to Quality management, in practice none understood themselves to be responsible, so OIG recommends a revision to provide specificity. Since Supervisor admitted that she did not know how to handle the matter because of her recent ascent to management, OIG recommends inclusion of updated error handling in supervisor training. Because Forensic Analysis Division Director admitted this error simply "fell through the cracks," OIG recommends retraining and inclusion of Error Review as a permanent agenda item in the bi-weekly meetings Forensic Analysis Division Director discussed. OIG also recommends that HFSC change its handling of contractors to assure the contractors' understanding of their Quality responsibilities and duties in general.

II. ERROR STANDARD

The Quality Manual (see Exhibit A) sets the standard to report any nonconformity to Quality management. Nonconformities must be reported when they involve "issues regarding the quality of technical services." If the error has to do with the quality of HFSC's technical services, Quality management must determine whether and where the error fits on the three-level scale, i.e., Class I, Class II, or Class III. According to the Quality Manual, without Quality management only "non-technical issues may be addressed through the appropriate chain of command."

A. FACTS

Instead of determining whether the May 2015 error was an "issue regarding HFSC's technical services," OIG found individuals and documents used a plethora of inappropriate and different rules of thumb to determine whether or not the May 2015 error was reportable, to whom and how:

(1) "Because we run thousands and thousands and thousands of tests and we are working with individuals that are human beings and they can only be as perfect as humanly possible. They are going to make a mistake. Now if they were doing it intentionally and sabotaging the work then that is professional negligence…more towards misconduct." (Forensic Analysis Division Director);

(2) "When the incident happened first we thought it could have been a one-time mistake. We decided if it happened again we would issue a corrective action. If it happens a second time it is no longer just a random error. It becomes a systemic error and that is something we need to address. We need to have some type of protective action and corrective action in place." Toxicology Manager explained that a CAPA is not considered a disciplinary form….We don't want to penalize people because then they will hide the problems. We want to be as transparent as possible….If a person is just careless then discipline should be taken." (Toxicology Manager);

(3) "At the time we thought just be really careful and don't do it again. When it was repeated [in October] that's when we knew there needed to be a CAPA." (Analyst #1);

(4) "Because it happened more than once and there was a change to the recipe forthcoming." (Analyst #2);

(5) "When we do the CAPA process we have a little chart and it can be a corrective action, an incident, or room for improvement basically. It can go three different ways." An incident form is used in the initial phase of reporting the non-conformance to the Quality Division." (Forensic Analysis Division Director);

(6) "We did an incident report and it was made into a CAPA because we were going to actually change the procedure." (Analyst #1);

(7) Is it safe to say an incident is something that would not require a change in policy? "Right. Sometimes it doesn't rise to that level." (Forensic Analysis Division Director);

(8) An occurrence (Quality manual);

(9) A nonconformity (Quality manual); and

(10) "Affected the evidence (Quality Director).

Forensic Analysis Division Director stated: "Looking back we should have made it an incident right from the get go. Obviously a sample is contaminated." However, the flow chart she provided as a current teaching tool is part of the problem. Forensic Analysis Division Director titled it "HFSC CAPA/Incident Documentation Flow Chart," leaving in place the potential for the next analyst to wonder whether something rises to the level of an "incident" or a "CAPA" and therefore requires the use of the flow chart.

B. FINDINGS

OIG finds that the root cause of this classification error is toxicology management's failure to promptly report the error to Quality management and to await Quality management's decision on the error's classification level before making further documentation and reporting decisions. OIG finds that the Quality Manual sets the correct and broadest standard for error reporting and that standard is whether the error involves an "issue[] regarding the quality of [HFSC's] technical services." Contaminating an evidence sample, no matter how inadvertently, is an issue regarding the quality of the lab's technical services.

Had the May error been correctly reported, the Quality Director could have checked then with other labs or HFSC's own consultant to discover that this was a common error with the Hamilton 600 instrument. The Quality Director could have classified the May 2015 error as a Class III error and implemented the preventative action plan.

> Class III errors are inconsistencies having minimal effect or significance on quality, are unlikely to occur, are not systemic, and do not affect the fundamental reliability of the Center's work product. Class III nonconformities include administrative or transcription errors… Class III errors are corrected and documented. If the same error occurs for the same staff member or under the same circumstances, then the error may be elevated in class.

If there were no information about prior issues with the Hamilton 600 instrument and the preventive action had unwelcome side effects such as excessive use of the initial blood tube, the Quality Manager could still have classified the error as a Class III error and documented that decision. In the unlikely event that a manager reported to Quality management a matter for which no corrective action was possible or appropriate, not even a reminder, a refresher, or a retraining, the Quality Director could make and document that decision.

OIG sustains the concern that the May 2015 error was not immediately correctly classified as an "issue regarding the quality of [HFSC's] technical services," resulting in an inappropriate delay in correct documentation.

C. RECOMMENDATIONS

OIG recommends the Quality manual be reviewed for amendment making the responsibility and the reporting standard clearer. OIG also recommends appropriate retraining upon completion of the amended Quality Manual.

III. TFSC SUBMISSION

The TFSC requires all forensic crime labs to report professional negligence or professional misconduct to the TFSC. Tex. Code. Crim. Proc. 38.01. According to TFSC, "professional misconduct" means:

> The actor, through a material act or omission, deliberately failed to follow the standard of practice generally accepted at the time of forensic analysis that an ordinary forensic professional or entity would have exercised, and the deliberate act or omission would substantially affect the integrity of the results of a forensic analysis. An act or omission was deliberate if the actor was aware of and consciously disregarded an accepted standard of practice for a forensic analysis.

"Professional negligence" as defined by TFSC means:

> The actor, through a material act or omission, failed to follow the standard of practice generally accepted at the time of forensic analysis that an ordinary forensic professional or entity would have exercised, and the negligent act or omission would substantially affect the integrity of the results of the forensic analysis. An act or omission was negligent if the actor should have been but was not aware of an accepted standard or practice required for a forensic analysis.

TFSC also provides guidelines on when to report an irregularity that may rise to the level of professional negligence or misconduct--a category TFSC describes as "Significant Irregularity in the Laboratory."

> Please note that the outcome of any particular criminal case should not be a consideration in your decision regarding whether to disclose an issue to the Commission. You should disclose any significant laboratory irregularity regardless of the criminal case outcome, and regardless of whether the quality controls in the laboratory caught the issue of concern before a final report was issued to the customer. When using the term "significant irregularity," we refer to facts that, if true, would indicate the existence of negligence or misconduct such that the integrity of the forensic examination, the individual forensic examiner, or the laboratory as a whole would be called into question.

Obviously, the analysts did not commit "professional misconduct" by pushing the wrong button on the Hamilton 600 instrument, requiring the unsealing of the secondary blood tube. OIG did not discover in its investigation "a standard of practice" requiring the pushing of the correct button on the machine. Certainly the analysts did not purposely fail to follow a standard practice. Alternatively, TFSC might see pushing the correct button as part of the standard of care and that the push-button error occurred three times without a report to TFSC. TFSC might also find that the integrity of these blood tests was lessened by requiring the unsealing of the second blood vial and removing the second vial as a "fail-safe." This guessing game cannot be won, but

it can be avoided. The TFSC provides for labs to voluntarily, not mandatorily, self-report. If performed within the same 30-day time frame, it could include a notice:

> HFSC does not believe analyst error involving accidentally pushing the wrong button on an instrument rises to the level necessary for self-disclosure, but in a desire to collaboratively provide information that could assist other labs, HFSC self-discloses the following along with its preventative action plan.

OIG does not have jurisdiction to determine what TFSC should decide about whether "any negligence" constitutes "professional negligence." However, going forward OIG recommends that HFSC consider avoiding this repeating conundrum by self-disclosing to TFSC all classes of errors.

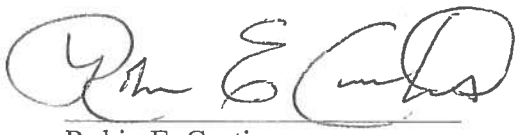
IV. DEFENSE NOTIFICATION

The anonymous complainant alleged that HFSC did not notify the defendant on any of the three occasions that the analyst accidentally ruined the first blood tube sample by pushing the wrong button on the Hamilton 600 instrument, requiring the unsealing of the secondary blood tube. Forensic Analysis Division Director and Toxicology Manager and Supervisor took the position that HFSC notified the defense with the sentence in the reports: "During sample preparation, the specimen became unsuitable for analysis." However, Forensic Analysis Division Director admitted "we should have been clearer." OIG agrees. Certainly the report put both sides on enough notice to ask further. While OIG did not find a requirement that the lab notify either side with any particular explicitness of the details of how a sample became "unsuitable," both sides need enough information to judge whether whatever caused the first vial to "become unsuitable" could call the analysis of the second vial into question.

OIG also noted the confusion among those interviewed about whether to notify either side pursuant to Section 6 of the Quality Manual (issue dated 3/30/15) which states: "The customer will be notified if the proposed analysis requires the consumption of all the evidence." Many wondered whether exhaustion of a complete vial, even though the lab had the back-up/secondary vial, constituted "consumption of all the evidence." Senior Analyst opined that he would notify both the submitting agency and the defense attorney any time the second vial of specimen was unsealed and used. Analyst #1 also asked management whether she should ask the customer (the ADA) whether to unseal the second tube knowing that though there will be plenty of blood for another defense test, "there will no longer be an unopened tube in case the defense wants independent testing."

OIG found no legal requirement that HFSC maintain an unopened blood vial. Therefore, HFSC can make a management decision on the issue. OIG recommends that HFSC make a decision and establish procedures and policy in this area.

Should you have any questions or need additional information, please feel free to contact me directly.



Robin E. Curtis
Inspector General

EXHIBIT A

Quality Manual Section on Nonconforming Testing Work
(Issued March 30, 2015-- in effect at time of May 2015 incident)

4.9 Control of Nonconforming Testing Work

4.9.1 Issues regarding the quality of technical services provided by the Center are brought to the attention of the appropriate section manager and the Quality Director, or their designee(s). The Division Directors, Quality Director, section manager, DNA technical leader and (in some instances) the CODIS administrator have the authority to halt (or resume) work in the Center and implement other necessary short-term responses to non-conformities.

Class I errors are those that have an immediate impact on the quality of the Center's work product. Class I non-conformities include false identifications and false positive results.

Class II errors may affect the quality of the work, but are not serious enough to cause immediate concern for the over-all quality of the Center's work product. Class II non-conformities include missed identifications and false negative results.

Class III errors are inconsistencies having minimal effect or significance on quality, are unlikely to occur, are not systemic, and do not affect the fundamental reliability of the Center's work product. Class III nonconformities include administrative or transcription errors.

The Quality director will insure that Class I and Class II issues are brought to the attention of the appropriate Division Director and manager. Class I and Class II errors will be fully documented and reported using a Corrective Action Form. (See 4.11) The manager or technical leader is responsible for investigating and reporting the occurrence to the Quality Division in a timely fashion. The investigation includes a review of any affected case work, root cause analysis and corrective action(s) taken to prevent a recurrence. The nature of the nonconformity dictates whether immediate action is necessary. Common sense must be employed when determining what constitutes nonconformity. Minor departures from accepted policy will normally require only a correction. The issuance of an amended report will serve as customer notification.

Class III errors are corrected and documented. If the same error occurs for the same staff member or under the same circumstances, then the error may be elevated in class.

Non-technical issues may be addressed through the appropriate chain of command. If necessary, the Division Director, manager, and/or Quality Director may work together to address thus type of concern. (See 4.7 and 4.8)

Refer to the HFSC *Progressive Corrective Action* policy for additional information.

Customers will be notified if their casework is recalled.

While following the HFSC *Third Party Communication* policy, top management will confer with the HFSC general counsel who will notify the HFSC Board of Directors, accrediting bodies, the Texas Forensic Science Commission and/or the appropriate attorney groups (i.e. district attorney offices) within 30 days of determining that a Class I nonconformity has occurred. This notification is also required in situations related to the following: intentional misconduct by a technical staff member, misrepresentation of education, training or experience; and other situations or conditions that raise immediate and/or significant concerns affecting the quality of the Center's work or the reliability of its test reports.

....

4.11.2 Root Cause Analysis

The first step in the corrective action investigation is an effort to determine the root cause of the apparent nonconformance. This process is conducted at the direction of the Quality Director. If the cause is not obvious, an analysis of potential causes will be conducted using a common sense approach. The HFSC frequently uses the *Five Whys* approach to determine root causes but other approaches may be used.

4.11.3 Selection and Implementation of Corrective Actions

Corrective actions will be taken where needed to eliminate the root cause of the nonconformance and to prevent a recurrence. These actions will be documented using the CAR form. The Quality Division maintains signed copies of these records.

Depending on the nature of the problem or error, appropriate corrective action(s) may include the following:

- If the error is determined to be in the method, the method may be removed from use on casework, modified, or given additional controls as necessary. Other cases in which the same method was used may be reviewed.
- If the error is determined to be with an instrument or other equipment used in the test, the error will be corrected and documented. Other cases in which the same instrument or equipment was used may be re-evaluated and appropriate action taken.
- If the error rests with the staff member it will be determined if the error was the result of inadequate or inappropriate training or is an isolated incident not likely to occur. If the original training is found to be faulty, appropriate additional training or evaluation will be completed. If the original training is determined to be adequate, the review will attempt to identify the specific cause of the problem or error. Actions take n to

address personnel issues may be confidential and may be handled by HFSC Human Resources in accordance with the Progressive Corrective Action Policy.

- If the error is found to be administrative or clerical in nature, the documentation and review process will be studied and revised, if appropriate, to minimize the recurrence of this error.

Corrective actions will be of the appropriate degree and magnitude to correct the problem and reduce the risk of occurrence. The Quality Director is responsible for follow-up and close-out of the corrective action process.