Final Report of the Indiana Board Prepared Pursuant to Indiana Statute IC 10-20.1

For

Governor Mitchell E. Daniels, Jr.

and

The Indiana General Assembly

Brian C. Bosma, Speaker of the House

Sen. David Long, Senate President Pro Tempore

August 30, 2012

Board
Linda L. Chezem, Chair
Dr. James E. Klaunig
Michael M. Medler

Executive Summary

Based on data provided by the Indiana Criminal Justice Institute the economic costs in Indiana from all crashes are approximately $4 billion. Nearly 30% of this total is caused by drunk drivers or $1.2 billion annually. Obviously, the strength of impaired driving laws in Indiana rely on the science of forensic toxicology as it applies to breath and blood alcohol testing as well as blood and urine testing for drugs. The integrity and credibility of the Indiana State Department of Toxicology (ISDT) has a direct impact on all public safety aspects of impaired driving in Indiana. The protection of the motoring public and the integrity of the criminal justice system depends on the strength of the science conducted by ISDT.

Toxicology is an important piece of the evidentiary puzzle. The science of toxicology must be conducted with adequate resources, rigorous oversight and open dissemination of the knowledge it produces. Good science protects the rights of defendants and victims when placed into the adversarial process of our justice system. Notwithstanding, excuses are not being made for any issues related to system failures within the ISDT. However, the overall development of forensic science is evolving at a rapid rate. ISDT must follow scientific methods based on scientific research and validation studies for forensic science. It is essential that the ISDT move as quickly as possible toward accreditation, strategic planning, appropriate staffing and funding. The goals and objectives of ISDT should be to serve the citizens of Indiana and the public safety community. The Board has relied on the information provided by Indiana University School of Medicine, ISDT and various state agencies to prepare this report for the Governor and the Legislature.

The Board made interim recommendations and now makes additional recommendations that are detailed later in this report:

1. Hire a new Director of the State Department of Toxicology with a background in the leadership and management of an accredited forensic laboratory. (Accomplished April 2, 2012)

2. The Board recommends that the ISDT immediately set its goal to be accredited by the American Board of Forensic Toxicology (by the end of by 2013) and accreditation by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) by the end of 2016.)

3. The Board recommends that an effective continuing education/training plan be instituted for the staff of the ISDT.

4. The Board recommends that a review of the current training program and training requirements be undertaken by both internal and external reviewers. The recommendations from the review shall be in the administrative code.

5. The Board also recommends that a "training coordinator or educator" position be established with credentials in adult education to ensure high quality instruction.

6. The Board recommends that ISDT provide continuing education to the legal community.

7. The Board strongly recommends that a permanent oversight board be appointed for the ISDT and that legislation be enacted to define the members, terms and powers of the advisory board. The authorizing legislation shall provide that the oversight board approve all fees for training.

8. The Board recommends that an organizational chart and manning table be developed as soon as possible to outline the current and future positions needed within the ISDT.

9. The board recommends the immediate hiring of the additional doctoral toxicologists by the end of 2012.

10. The Board recommends that new rules for the use and operation of the new breath test instruments be promulgated as soon as possible.

11. The Board recommends that adequate funding be provided to the ISDT so that this organization may properly provide scientifically valid results in a timely manner.

12. The Board recommends that the oversight board contract with recognized subject matter experts to conduct a review to assess the current and future needs of the ISDT with regard to funding

13. The Board recommends that a strategic plan for the ISDT should be developed as soon as possible.

14. The Board recommends that a plan be developed and implemented to secure both the "data" generated by ISDT and evidentiary samples held by the ISDT.

15. The Board recommends that an annual report be generated by the ISDT for the legislature and also be made public electronically on the ISDT website.

Background

In the spring of 2010, the Indiana Criminal Justice Institute requested that an assessment team be formed that included Senator Thomas Wyss, State Representative Peggy Welch, Dr. Michele Glinn, Michigan State Police Forensic Toxicologist, Michael M. Medler, Director of the Indianapolis-Marion County Forensic Services Agency Marion County Forensic Lab and former Indiana Court of Appeals Court Judge Linda Chezem, to assess and report on the "Operations and Structure of the Indiana State Department of Toxicology". This report was to be forwarded to the Governor's Council on Impaired and Dangerous Driving.

The assessment team was requested to review the 2008 recommendations made by the National Highway Traffic Safety Administration; to analyze and consider what might be the optimal organizational structure of the Indiana State Department of Toxicology; to assess the forensic services provided by the Indiana State Department of Toxicology; and to make recommendations for improvement. To that end the committee met with Indiana University School of Medicine and Indiana State Department of Toxicology staff and administration; reviewed documents provided by ISDT; reviewed applicable statutes and regulations; and reviewed information received from criminal justice professionals and former directors of ISDT.

- The assessment team reported the following findings:
    - Serious delays in blood alcohol and toxicology testing on blood.
    - Destroying evidentiary blood samples without the direct knowledge of prosecutors.
    - The lack of any movement toward accreditation of the laboratory.
    - Breath testing instruments that were purchased and stored with no plan for implementation in the field.
    - Breath test training for law enforcement officers was being delayed with no plan going forward for fixing the problem.
    - The failure of the ISDT to meet with stakeholders and legal professionals to address the issues facing the ISDT which had been recommended in the 2008 NHTSA assessment team report but ignored.
    - The placement of the Indiana State Department of Toxicology in the IU School of Medicine is not compatible with the IU School of Medicine's mission, nor does it fit into the modern day era of operating forensic service laboratories.
- The assessment team recommended the following:
    - The ISDT must obtain accreditation.
    - The Governor's Council propose and support legislation to accomplish the needed legislative changes which includes moving the ISDT from the jurisdiction of the IU School of Medicine to an independent new state agency to carry out these and other recommendations.
    - The Governor's Council should create a subcommittee to provide oversight and guidance to ensure that the ISDT is responsive to the people of Indiana.

Senate Bill 431 was passed in the next legislative session and signed by the Governor into law.

Senate Bill Enrolled Act 431-2011 removed the Department from the Indiana University School of Medicine (IUSM) and made it an independent state agency effective July 1, 2011. Governor Daniels appointed the Toxicology Advisory Board (Board) members on June 16, 2011. The three members are Dr. James E. Klaunig, Linda L. Chezem, retired appellate court judge and Michael M. Medler, Director of the Indianapolis-Marion County Forensic Services Agency.

On June 24, 2011, the Board accepted as its charge the following language:

The Board is established to assist in the transition of the state department of toxicology from the Indiana University School of Medicine to the state department of toxicology under IC 10-20. The Board shall provide guidance on: (1) the transition to the department; (2) obtaining accreditation by a nationally recognized organization that sets toxicology standards; and (3) recommendations for additional legislation needed regarding the ongoing operations of the department of toxicology. (f) The Board shall deliver a report to the governor and the legislative council by September 1, 2012. The report to the legislative council must be in an electronic format under IC 5-14-6. In addition to providing guidance on operational and organizational matters, the advisory Board's scope of work will include but not be limited to: Establish the qualifications and search for a permanent director; Promulgation of rules and deployment of breath test instruments as well as development of a program for the certification of public safety officials for the operation of the equipment;
Laboratory accreditation under ISO 17025 as applicable to forensic laboratories and gain an understanding of the progress and results of the ongoing technical review of cases.

Toxicology Advisory Board Proceedings

The Board has issued one interim report. Since the first interim report, the Board has held meetings and sought additional information to better understand the operations of the department. The board has also reviewed the report from The National Forensic Science Technology Center (NFSTC) which was contracted by the Governor's Office of the State of Indiana to perform a needs assessment of the Indiana State Department of Toxicology (ISDT). The agenda and the minutes for each of the meetings are posted on the web site at *http://www.in.gov/cji/3504.htm*. The report from National Forensic Science Technology Center (NFSTC) is attached in the appendix.

The Board held an organizational meeting on June 24, 2011 during which Judge Linda Chezem was selected as chairperson. Subsequently the board held a total of nine (9) public meetings and three (3) executive sessions which addressed past and current activities, and the operations of the ISDT. Minutes of these meetings are available at http://www.in.gov/cji/3504.htm and in the Appendix attached to this document.

The Board sought public comment from stakeholders about the alcohol breath testing program, the laboratory part of the ISDT program as well as the education and training mission. These efforts were calculated to inform the recommendations made by the Board as well as to engage the broader community in understanding why ISDT matters to the safety of the Indiana roads as well as to the justice system. The following recommendations are made with the recognition that the implementation will be determined by the Governor and the Indiana General Assembly by the Board in its advisory capacity.

Initial meetings consisted of fact findings to understand more fully the current status of the ISDT including qualifications and job descriptions of personnel, organization of the ISDT, updates on drug and breath testing, and educational and training activities of the department. In addition the Board attempted to gain an understanding of the rationale, approach, progress and results of the ongoing technical review of cases (referred to as the audit) initiated by a former director of the department.

Recommendations of the Toxicology Advisory Board

Hire a Permanent Director

Based on multiple public meetings, fact finding procedures by the Board, input from members of the ISDT as well as input from National Forensic Science Technology Center (NFSTC) a number of recommendations were made to the governor's office in response to the charge of the Toxicology Advisory Board. The immediacy of several issues required prompt action and these issues and recommendations were detailed in the interim report of July 22, 2011. Most notably was the need to hire a permanent director.

The Board provided a listing of qualifications and job duties to the Governor's office for the recruiting of a new Director for the ISDT. A member of the Board assisted in the search and interviews for a new director. After a national search, Mr. Edward Littlejohn was appointed as the first director of the ISDT on April 2, 2012 after its transfer to the state from the IU School of Medicine. Director Littlejohn has extensive administrative and scientific experience in the field of forensic science and should do well in stabilizing the department as well as leading the ISDT through the challenges it faces in the coming years.

Accreditation

Forensic toxicology involves the measurement and analysis and interpretation of drugs, alcohols, and other toxic substances in human tissue and liquid specimens in the context of the medico legal environment. As the science of toxicology and specifically forensic toxicology has advanced in the past several decades, the need to establish standards for the practice of forensic toxicology, in the laboratory has been increasingly recognized. The process of accreditation by a nationally accepted accreditation body is not the norm rather it is the exception in the area of forensic toxicology. The Board recognizes this need especially in lieu of the difficulties and problems that have been revealed in the laboratory in the past.

The two accreditation boards are the American Board of Forensic Toxicology (ABFT) and the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). The latter includes the "management practices" as well as the sciences and is much more demanding in their criteria for accreditation which will require more time for ISDT to achieve this standard.

The Board recommends that the ISDT immediately set its goal to be accredited by the American Board of Forensic Toxicology (by the end of by 2013) and accreditation by the American Society

of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) by the end of 2016.)

Education and Training

Education and training was an integral component of the mission of ISDT from its inception in 1957 until 2003. Until 2003 all directors of the ISDT were also full tenured professors at Indiana University with international reputations in toxicology who participated in the training of medical and graduate students in toxicology and pharmacology. This approach was changed in 2003 when the qualification of the director no longer was required to qualify as a professor in the Indiana University system. The Board recognizes the importance the mission of education and training at the ISDT .Three areas of education and training were recognized as being needed. These include:

A. ISDT employee/staff training

It is a critical requirement of most accreditation boards that a program for the further training and education of staff within the laboratory be addressed. Further training and education of the staff is also a morale builder. This can be in the form of in-service training, sending staff for continuing education course and participation of staff in scientific meeting devoted to forensic toxicology. Besides training in scientific methods, techniques and instrumentation, a particular need is the implementation of courtroom testimony education for the technical staff since the presentation of their results, interpretation of results, handling of specimens etc. in depositions, and in court is required. The in service staff training can be accomplished via instruction by professional staff; however, the contracting of individuals to come to the ISDT and present needed instruction may be advantageous.

The Board recommends that an effective continuing education/training plan be instituted for the staff of the ISDT.

B. Training, Certification and Recertification of Breath test operators and other law enforcement personnel.

A statutory requirement of the ISDT is the training, certification and recertification of breath test operators. Indiana was a trailblazer in this area and a certification course established by Dr. Robert Forney was used as the model for both national and international training of breath test operators and mangers. To facilitate the training of non Hoosiers, a program developed by former Indiana State Police Captain Robert Borkenstein was initiated at IU Bloomington based on the ISDT training of breath test operators in Indiana. As a statutory requirement, the training and retraining of breath test operators must be set out in the Indiana administrative code. The Board cautions that any reduction of hours committed to this important activity cannot be reduced to simply "push a button" on the breath test instrument. One consideration would be to couple the breath test training school with the field sobriety training, thus producing law enforcement personnel that have improved training and understanding of impairment, measurement and analysis of samples for drugs and alcohol.

Alternately, the department might consider contracting the training of the breath test operators to an outside entity to possibly save on personnel costs. Caution must be raised that quality control and evaluation procedures are in place to ensure proper training if the education is contracted outside the

ISDT. Besides the certification – breath test course, the statutory requirement for recertification of breath test operators is every two years. This should be continued with the year time frame as the longest acceptable period for recertification. The current requirement of four hours training in recertification should be continued – not reduced. The web based online recertification in current use should be reevaluated. Concerns by the Board were raised over the completeness of the course work offered in the web based recertification. A return to regional, in person recertification should be strongly considered.

The Board recommends that a review of the current training program and training requirements be undertaken by both internal and external reviewers. The recommendations from the review shall be in the administrative code.

The Board also recommends that a "training coordinator or educator" position be established with credentials in adult education to ensure high quality instruction.

C. Education of legal community

Although not a statutory requirement, the Board recommends that ISDT provide continuing education to the legal community including the judiciary on issues relating to forensic toxicology. This can be provided through ISDT staff or contracted to an outside entity through grants and/or contracts. Toxicology is a unique science and further understanding of the methods and interpretations from toxicology labs is important in ensuring that science is properly interacted with the law.

The Board recommends that ISDT provide continuing education to the legal community.

Formation of a Permanent Oversight Board

The Board strongly recommends that a permanent advisory/ oversight board be appointed for the ISDT and that legislation be enacted to define the members, terms and powers of the advisory board. After review, it was apparent that a major fault in the functioning of the ISDT for the past several years was the lack of credible oversight. The Board recommends that the oversight board should include scientific expertise, especially in toxicology (at least two members), representatives of the defense and prosecution, a representative of law enforcement, a current or past member of the judiciary, and members of the legislative branches. Ample administrative support from the state should be provided. This board shall provide advice to the director for the ISDT on operational laboratory matters and on fees for training.

The Board strongly recommends that a permanent oversight board be appointed for the ISDT and that legislation be enacted to define the members, terms and powers of the advisory board. The authorizing legislation shall provide that the oversight board approve all fees for training.

Organizational Chart

Although required by accrediting bodies, the Board recommends that an organizational chart and manning table be developed as soon as possible to outline the current and future positions needed within the ISDT. The Board proposed a model for consideration during the fall of 2011 (see appendix). One area of immediate need includes the hiring of additional doctoral level toxicologists. The board recommends the immediate hiring of the additional doctoral toxicologists by the end of 2012. A second area of need is the breath testing program which has received inadequate attention in recent years. Additional personnel in the oversight and technical handing of the breath test instrument should be hired. The current inspector positions should be reevaluated and consideration given to the hiring of technicians that are trained in the repair and function of the breath test instruments. The newer breath test instruments are highly computerized and more sophisticated technically than previous models used in Indiana. Personnel that are trained in electronics, computers and instrumentation are needed for this area of the ISDT. Other states contract out these services and the ISDT should evaluate that approach as a possible means for the maintenance and operation of the breath test instruments. Also the breath test division needs an individual to provide leadership for the breath test program. Finally, a third needed area for both the drug lab and the alcohol program is the need for a Quality control/ Quality assurance program. The individual hired to be part of this program would ensure proper procedures are developed and followed by the ISDT analytical lab and breath test program. While this position will be required for accreditation the Board recommends that this position be filled as soon as possible. The Quality Assurance (QA) Manager must have a clear reporting line to the director. The QA responsibilities may be included with one of the toxicologists positions in the lab.

Board recommends that an organizational chart and manning table be developed as soon as possible to outline the current and future positions needed within the ISDT.

The board recommends the immediate hiring of the additional doctoral toxicologists by the end of 2012.

Placement of Breath Test Instrument(s) and the Promulgation of New Rules

Over 200 intoximeter breath test instruments were purchased by a former director of the ISDT in 2008. The instruments have been "warehoused" since the purchase. In order to properly place the instruments in the field (jails, police agencies) for operation, new rules (IAC 260) must be promulgated regarding the operation of the instruments (the approved method of operation) and breath test operators must be instructed and certified on their proper operation. The Board recommends that new rules for the use and operation of the new breath test instruments be promulgated as soon as possible. Once the rules are promulgated, a plan to certify the breath test operators on the proper use and performance of the instruments will need to be devised.

The Board during public hearing solicited and received input on the rules for the approved method. Two major concerns were expressed regarding the new rules. These included how long and where the period of observation (minutes) prior to performing the breath test should be (15 or 20 minutes and at the breath test site or while in control of the arresting officer). The second issue was how many tests need to be performed on each subject. Arguments for both a single test as well as two tests have been presented. In the fifty US States, some states perform two tests while others perform one test. With regard to the

observation time and place of observation of the subject to be tested, most states utilize a 15 or 20 minute period of observation. The Board has no recommendations regarding either of these two issues.

The Board recommends that new rules for the use and operation of the new breath test instruments be promulgated as soon as possible.

Funding for State Department

The Board recommends that adequate funding be provided to the ISDT so that this organization may properly provide scientifically valid results in a timely manner. The costs associated with the current scientific performance of the ISDT laboratory are not insignificant but pale in the costs in time and money if the results obtained are not recognized as accurate. The process of accreditation adds considerable cost to the yearly operating budget but is an essential and required component of moving the ISDT forward. Equipment and personnel in forensic toxicology are the two major cost drivers for the ISDT but represent the foundation of an excellent functioning organization. The greatest waste of money is the production of scientific results that are not admissible into evidence. The Board recommends that the oversight board contract with recognized subject matter experts to conduct a review to assess the current and future needs of the ISDT with regard to funding. This should be completed after a strategic plan and organization chart are developed by the ISDT.

The Board recommends that adequate funding be provided to the ISDT so that this organization may properly provide scientifically valid results in a timely manner.

The Board recommends that the oversight board contract with recognized subject matter experts to conduct a review to assess the current and future needs of the ISDT with regard to funding.

Strategic plan

The Board recommends that a strategic plan for the ISDT should be developed as soon as possible. Input from external parties familiar with forensic toxicology and with the ISDT should be sought and incorporated into the strategic plan developed by the director. Accreditation bodies require a strategic plan and organization chart as well as grant funders.

The Board recommends that a strategic plan for the ISDT should be developed as soon as possible.

Security

The Board recommends that a plan be developed and implemented to secure both the "data" generated by ISDT and evidentiary samples held by the ISDT.

Annual Report

The Board recommends that an annual report be generated by the ISDT for the legislature and also be made public electronically on the ISDT website. The annual report should include but not be limited to the number of tests performed on breath test instruments, number of officers certified as breath test operators, number recertified, number of blood alcohol samples performed, average turnaround time for lab samples, listing of personnel in the department, number of breath test schools given, number of recertification school taught, number of applicants on waiting lists for breath test school attendance, average waiting time, number of drug analysis performed , type of drugs found etc.
A breakdown of the above information by quarter or monthly would be preferred. The report should be provided in September of each year to allow for legislative action and budgetary considerations as needed. In addition, it is important that the ISDT website as "its window to the world" is updated on a routine basis.

The Board recommends that an annual report be generated by the ISDT for the legislature and also be made public electronically on the ISDT website.

Submitted: August 30, 2012

Linda L. Chezem

James E. Klaunig

Michael M. Medler

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The First Interim Report by the Toxicology Advisory Board
(July 22, 2011)

1. Overview of the Indiana State Department of Toxicology.

Senate Bill Enrolled Act 431-2011 removed the Department from the Indiana University School of Medicine (IUSM) and made it an independent state agency effective July 1, 2011. Governor Daniels appointed the Toxicology Advisory Board (Board) members on June 16, 2011. The three members are Dr. James Klaunig, Mr. Mike Medler and Linda L. Chezem.

After appointment, the Board held several public meetings to review the current state of the agency in a fact finding exercise.

These meetings included:

2. The Board held an organizational meeting on June 24, 2011.

Linda Chezem was selected as chairperson.

The Board, after reviewing the statute, accepted as its charge the following language:

> *The toxicology advisory Board is established to assist in the transition of the state department of toxicology from the Indiana University School of Medicine to the state department of toxicology under IC 10-20. The Board shall provide guidance on: (1) the transition to the department; (2) obtaining accreditation by a nationally recognized organization that sets toxicology standards; and (3) recommendations for additional legislation needed regarding the ongoing operations of the department of toxicology. (f) The Board shall deliver a report to the governor and the legislative council by September 1, 2012. The report to the legislative council must be in an electronic format under IC 5-14-6.*
>
> *In addition to providing guidance on operational and organizational matters, the advisory Board's scope of work will include but not be limited to:*
>
> - *Establish the qualifications and search for a permanent director;*
> - *Promulgation of rules and deployment of breath test instruments as well as development of a program for the certification of public safety officials for the operation of the equipment;*
> - *Laboratory accreditation under ISO 17025 as applicable to forensic laboratories and*
> - *Gain an understanding of the progress and results of the ongoing technical review of cases*

The Board reviewed the proposed Memorandum of Understanding (MOU) between the State and IUSM for transition of the laboratory operation. With a few suggestions, the Board

recommended that the MOU be put in place as soon as possible. As a part of the MOU, the points of contact for the Board and for IUSM for the exchange of information were established. The Board reviewed the documents available to it regarding the technical paperwork review of the data from laboratory testing from 2007 to 2008 by outside consultants.

Though many have referred to this review as an audit, it is only a review of paperwork, not actual sample retesting. Instead, a "technical review of cases and the associated test results" is the language in the "agreement for consulting services" with the ISDT.

3. The Board held its second meeting on June 29, 2011.

The Board met at the Department of Toxicology offices and laboratories and met with the management team from the University as well as some staff members from the ISDT, at their request to acquire more information and context.

The Board noted the need for more precise and complete information and documentation to sort through the management, organizational structure, and senior leadership at the Department.

4. A third meeting of the Board was held on July 6, 2011 at the ICJI offices in Indianapolis.

The Board discussed cost and process of the paperwork review of the laboratory testing documentation for the 2007-2008 periods. At this time, the amount paid and or due to the consultants is over $250,000 and the cost to copy the documents for the consultants to review the data is over $40,000. These costs do not include the cost of any retesting of samples identified as problematic by the technical review of cases.

5. A fourth meeting of the Board was held on July 15, 2011 at the ICJI offices in Indianapolis.

A discussion, by teleconference, with National Forensic Science Technology Center (NFSTC) occurred. The NFSTC is an organization that assists at a national level in helping forensic laboratories to attain accreditation as well as establishing the correct structure and leadership needed to meet ISO 17025 as applicable to forensic laboratories. The Board also discussed the issues that are facing the alcohol and impaired driving program and the immediate need for strong and capable leadership in the ISDT. In addition, other discussion of the results of the interviews, the review of requested documentation from the ISDT and need of further information occurred. The Board is also reviewing legislative needs related to the ISDT.

Preliminary Findings and Recommendations

Based on the initial meetings and review of requested information noted above, the Board has the following findings and recommendations.

1. The Board recommends that the Governor's Office officially appoint an interim director of toxicology for a term to last no longer than 6 months. There is a need for strong and competent leadership in the ISDT. An interim director should be appointed by the governor as soon as possible.

2. The Board recommends the Governor's Office to place a hold on the current contract and work completed by outside consultants until retesting of identified problematic cases is conducted.

a. The technical review of cases (which was a "paper" review of analysis, data, notes, etc. but did not include any retesting of the samples in question) initiated by the former director has revealed a number of structural concerns in the performance of analysis on several positive tests for THC and cocaine. After the technical review of cases ; the Board concluded that to properly and thoroughly examine the issues raised by this technical review of cases that further testing of the samples be performed by an outside, third party, laboratory. Until the re-analysis of the samples raised as questionable in the technical review of cases can be completed, it is scientifically unclear if the result reported is incorrect.
b. The Board recommends that an ISO 17025 accredited forensic laboratory perform these tests.
c. The results of the retesting shall be reviewed by consulting toxicologists and the Board and should be conveyed to the prosecutors, defense and public in understandable language. In other words, the explanations made should explain the significance of the findings and what they mean in lay language.

3. The Board recommends that the State develop plans for transition of the ISDT to include but not limited to the following:

a. The transition of personnel from the University to the State;
b. The transition of information technology (IT) systems from the University to the State;
c. The transition of the budgetary and finance aspects of the ISDT from the University to the State;
d. That the State develop security protocols for the ISDT and strictly review the ones currently in place to protect the sensitive and investigatory records of the ISDT;
e. That an full asset inventory be undertaken by the State; and
f. That procurement protocols are transitioned from the University to the State.

4. The Breath testing program is in need of immediate attention. The Board asked for information on the location, number and condition of the new instruments that were purchased by the lab previously that have not been placed in designated field locations.

The Board made the following recommendations for the breath testing program:

a. Confirm that the evaluation process for the new instrument selection and purchase was evaluated per the requirements of the Indiana code and regulations.
b. Confirm the reliability of the new instruments and their capacity to perform to the Indiana requirements.
c. As soon as the breath test instrument selection has been confirmed, promulgate the rules and develop a training and placement plan.
d. In addition, there appears to be no senior leadership of the breath test program. Leadership of the breath test program needs to be assigned immediately.
e. The training process – certification and recertification of officers needs to be evaluated as to the current process ensuring that the process is following proper scientific and administrative code requirements for the state of Indiana.
f. Develop a plan to maintain and certify the existing instruments.

5. A needs assessment of the ISDT is required.

The Board recommends that the State enter into an agreement with National Forensic Science Technology Center (NFSTC) The National Forensic Science Technology Center (NFSTC) is a 501(c) (3) not-for-profit corporation headquartered in Largo, Florida. Founded in 1995, the NFSTC provides quality forensic services including training, assessment, research and technology assistance to the justice and forensic communities. NFSTC receives funding from the National Institute of Justice and other federal agencies.

The assessment will advise the Board and the State with the development of a list of "task orders" to be selected, prioritized and completed by NFSTC to help move the ISDT forward.

6. Current legal representation and advice to the ISDT.

In the fact finding process, it became apparent to the Board that there is confusion on the legal representation of the ISDT. The Board recommends that the legal representation of the ISDT be resolved immediately by the State.

Toxicology Advisory Board

Minutes
Date: June 24, 2011
Location: Indiana Criminal Justice Institute (ICJI).

Board Members Present: Mike Medler, Dr. James Klaunig, Linda Chezem

Other Attendees: Cris Johnson, Gloria Downham, Ryan Klitzsch, Sebastian Smelko, Scott Newman, Mark Massa

1. The Toxicology Advisory Board (Board) held its organizational meeting on June 24, 2011. Linda Chezem was selected as chairperson.

2. The Board, after reviewing the statute, accepted as its charge the following language:

The toxicology advisory board is established to assist in the transition of the state department of toxicology from the Indiana University School of Medicine to the State Department of Toxicology. The board shall provide guidance on:
(1) the transition to the department;
(2) obtaining accreditation by a nationally recognized organization that sets toxicology standards; and
(3) recommendations for additional legislation needed regarding the ongoing operations of the department of toxicology.
(f) The board shall deliver a report to the governor and the legislative council by September 1, 2012. The report to the legislative council must be in an electronic format under IC 5-14-6.
In addition to providing guidance on operational and organizational matters, the advisory board's scope of work will include but not be limited to:

Establish the qualifications and search for a permanent director
Promulgation of rules and deployment of breath test instruments as well as development of a program for the certification of public safety officials for the operation of the equipment
Laboratory accreditation under ISO 17025
Gain and understanding of the progress and results of the ongoing audits

3 The Board reviewed the proposed MOU between State Budget Agency, the Office of Finance and Management, and IU School of Medicine for transition of the laboratory operation. With a few suggestions, the board recommended that the Memorandum of Understanding (MOU) as currently proposed by the Office of Finance and Management be put in place as soon as possible. As a part of the MOU, the points of contact for the Board and for IU for exchange information were recommended to be Linda Chezem and Dr. Scott Kriger.

4 The Board reviewed the documents available to it regarding the technical paperwork review of the data (referred to as the audit) from laboratory testing from 2007 to 2008 by outside consultants (Forensic Consultants). While the media and others have referred to this as an "audit", at this point in time, no scientific auditof the department as audit is used and commonly

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understood has been undertaken. Instead, a "technical review of cases and the associated test results" is the language in the "agreement for consulting services" with the ISDT. The Board considers this audit a paperwork audit and review.

5. The Board met with Mr. Scott Newman who explained his perspective of the work he had undertaken to include his assessment of the paperwork review (audit), personnel, and general operations. He indicated that the audit was complete on the THC and Cocaine testing from 2007 to 2008 and that the next samples audited would be the blood alcohols performed by the laboratory in that same time period. A question was raised by the board if the blood samples of those tests that the auditors found to be of concern were still available for retesting. He indicated he thought they were not available anymore. Mr. Newman is supervising all the correspondence with the attorneys. He has engaged in a collaborative exercise between Scott and Barnes and Thornburg. Basically, in preparation for third party requests for audit related material, Mr. Newman asked what kind of approach IU should take (without getting into details). He represents IU currently. After discussions with Mr. Newman, Judge Chezem stated a concern that just sending out audits reports without more specific information will cause a problem. The first question is who is representing whom and how do we handle the transition and move forward? Mr. Newman provided a organizational chart for the state department of toxicology. The chart indicated that he was directly responsible for the breath test program (training and instrumentation) Concerns were raised by the board to Mr. Newman over the "new" breath test instrument (Intoximeter) selection, placement in the state and promulgation of the appropriate rules for using these Intoximeter instruments

6. The board agreed to gather additional information about the consultants (Forensic Consultants), the selection process performed by the SDT director to secure this group of consultants and the process of the review performed by this group.

7. The board set the next meeting for June 29, 2011 at the Department of Toxicology. The board requested that toxicology staff be invited to meet with the board to be better inform the board's deliberations. Public notice will be posted again and each time that the Board ~~the~~

8. Agenda of meeting attached

9. Motion to Adjourn was made and passed

Toxicology Advisory Board

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Toxicology Advisory Board

Minutes

Date: June 29, 2011

Location: Department of Toxicology

Board Members Present: Mike Medler, Dr. James Klaunig, Linda Chezem

Other Attendees: Cris Johnson, Gloria Downham, Ryan Klitzsch, Sebastian Smelko, Debbie Reasoner

Toxicology Advisory Board

1. The board met at the Department of Toxicology offices and laboratories. The board met with and discussed the department strengths and needs with the following staff currently employed by Indiana University: Dr. Scott Kriger, Dr. Montforte, Gary Bracket, Joe Scodroe, Anna Hilgeman, Randall Higgins, Robert Lawson, and Fe Joven.

2. The discussion was broad and covered both the breath testing program as well as the laboratory program. The toxicology staff freely asked questions related to their employment status and were advised to work with the state personnel staff on the personnel and benefits issues.

Other items reviewed with the staff included the basic day to day computer operations. The department has servers that are connected to the IU server. Security access is controlled at different levels. Justice Trax is close to being fully operational.

3. Information was presented to explain some of the laboratory efforts. One problem noted by staff was that the lab was only reporting presumptive results in some cases. A report for a presumptive alcohol/marijuana positive would be issued and then sent out to a commercial lab because the state lab was not capable of doing it. The staff stated that their goal was to issue one report so that the need for presumptive testing would not be needed. The board stated that it is a good time to set a foundation to what should happen with the blood alcohol paperwork audit process before it gets underway. The board expressed concern over the confusion around the paperwork audit to include but not limited to: the lack of sample retesting; the established standards for the audit were not the standards used by the toxicology lab; audit conclusions and the supplemental notes on the limitations of the audit have been miscommunicated to the stakeholders (appendix 1) and the cost of the audit ($250,802 spent to date without a bid process; in addition $44,000 has been spend to copy the documentation to send to the auditors). A concern was voiced by Board members that it is necessary to put a frame work around what the paperwork audit means or doesn't mean and what should be done with the results and the communication of the results. While the scientific staff members were asked for comments in the letters sent to the prosecutors they were not asked to review the final letter sent. Both Dr. Montforte and Dr. Kriger were asked if they would testify to the results of the contracted audit since retesting of

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any samples in question was not a part of the audit. Both affirmed they would not. Dr. Kriger was asked why he signed the letters that were sent to the prosecutors. He stated that he was instructed to do so. No retests have been done as a result of the paper audit review. Dr. Kriger was asked if the blood samples of the cases that were identified by the auditors as a concern were available for laboratory retesting. He replied that they were available and that retesting could be performed. Currently it appears that most of the drug analysis in the state department is being sent out to commercial labs. Both AIT and National Medical Services are being used as vendors. Some concerns about testing at AIT were mentioned by staff members (in quality or the way it was reported). Apparently problems were encountered in the AIT results in efforts to retrieve the reports from the web.

4. During the interviews with staff, it was brought to the board's attention by several staff members that Department property has been lost or stolen. Concerns were also raised by the Board on the current storage conditions of the Intoximeters purchased by Dr. Wagner and not yet deployed.

5 Staff was asked if they had seen the organization chart that Mr. Newman provided. They all replied that they had only seen it recently. The Board agreed that a proper organization chart reflecting the transfer of the toxicology group from IU to the State be developed. The board also recommended that Dr. Montfort's contract be extended.

6. Departmental legal issues were reviewed with Mr. Joe Scodroe.

7. Many operational details were reviewed with staff that needs more explanation. The Board requested more complete and precise information and documentation to sort through the management, organizational structure, the leadership positions, and the qualifications of current senior leadership at the Department.

8. Public notice will be posted for the next meeting

9. Motion to Adjourn was made and passed

ATTACHMENTS 6-29-2011 Appendix 1

Toxicology Advisory Board

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APPENDIX 1

6-29-2011

may be acceptable.

3. On occasion there was no acknowledgement of failed ion ratios on the data and no manual integration; however, the results were reported.
4. There were several examples of calibrators that were included in the calibration curve that did not have acceptable chromatography and should have been eliminated.

Supplemental Notes on Limitations of this Review

Please note this type of Qualitative Review is subject to the following limitations and exclusions:

- The Review does not purport to draw conclusions about the legal admissibility or validity of the data.
- Only qualitative results are evaluated; no attempt has been made to verify the quantitative aspects of the report issued by the laboratory.
- The Review did not attempt to verify that the drug is present in the sample above the SOP reporting limit (lowest calibrator).
- Matrix-matched controls, though preferable, were not required by the review criteria.
- Only one negative and one positive control per analytical batch were required for acceptance.
- The Review accepted analytical batches spanning multiple days.
- Correct sample identification, preservation of chain of custody, and proper secure storage of specimens were presumed.
- The Review did not include an evaluation of the foundational method validation data (specificity; appropriate ion selection; carryover, etc.), nor did it review the documentation of standard or control preparation.
- The Review did not endeavor to determine if the analysis was in compliance with the SOP in effect at ISDT at the time.

Appendix A: List of Laboratory Accession Numbers and Review Results
Appendix B: Cocaine Review Data
Appendix C: Benzoylecgonine Review Data

APPENDIX 1

6-29-2011

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- Correct sample identification, preservation of chain of custody, and proper secure storage of specimens were presumed.
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Appendix A: List of Laboratory Accession Numbers and Review Results
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Appendix C: Benzoylecgonine Review Data

as plastic, glass, and silanized glass. It is not known under what conditions the samples in question have been stored.

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Please note this type of Qualitative Review is subject to the following limitations and exclusions:

- The Review does not purport to draw conclusions about the legal admissibility or validity of the data.
- Only qualitative results are evaluated; no attempt has been made to verify the quantitative aspects of the report issued by the laboratory.
- Only identifies the presence of the drug in the sample.
- The Report does not attempt to verify that the drug is present in the sample above the SOP reporting limit (lowest calibrator).
- Matrix-matched controls, though preferable, were not required by the Report's analysis.
- Results were reported without having complete knowledge of the calibrator or control matrix in all analytical batches.
- Only one negative and one positive control were required for acceptance.
- Correct sample identification, preservation of chain of custody, and proper secure storage of specimens were presumed.
- The Review did not include an evaluation of the foundational method validation data (specificity; appropriate ion selection; carryover, etc.), nor did it review the original documentation of standard or control preparation.
- Results were reported without having complete knowledge of the reference material used for standards or positive controls.
- The Review accepted analytical batches spanning multiple days.
- The Review did not require that a negative control be included in each extraction batch in multiple-day analytical batches.
- The Review recognized that batch worksheets contained no documentation for a check of the sequence.
- Only samples that were confirmed positive by the laboratory were reviewed; negative findings (non-detected samples) were not reviewed. Samples were regarded as non-detected if they were annotated or reported as such in the file or if the data suggested

APPENDIX 1 6-29-2011

there was no qualitative presence of the analyte due to an ion ratio failure *and* low analyte abundance.

- The Review acknowledged that data did not necessarily adhere to the SOP in effect at the time.
- The Review acknowledged that GC/MS instrument tune files may have been applied beyond 24 hours of their creation, and thus could have changed during the course of a multiple- day batch.

References on stability of analytes:

1. J.R. Johnson, T.A. Jennison, M.A. Peat, and R.L. Foltz. "Stability of delta 9-tetrahydrocannabinol (THC), 11-hydroxy-THC, and 11-nor-9-carboxy-THC in blood and plasma." *Journal of Analytical Toxicology.* 8(5): 202-4 (1984).

2. S. Dugan, S. Bogema, R.W. Schwartz, and N.T. Lappas. "Stability of drugs of abuse in urine samples stored at -20 degrees C." *Journal of Analytical Toxicology.* 18(7): 391-6 (1994).

3. M.A. Huestis. "Cannabis (Marijuana) - Effects on Human Behavior and Performance." *Forensic Science Review.* 14: 15-60 (2002).

Appendix A: List of Laboratory Accession Numbers and Reviewed Results
Appendix B: THC Review Data
Appendix C: THCA Review Data

Dr. Nearman's report

Very truly yours,

J. Robert Zettl

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Toxicology Advisory Board

Minutes

Date: July 7 2011

Location: Indiana Criminal Justice Institute

Board Members Present: Mike Medler, Dr. James Klaunig, Linda Chezem

Other Attendees: Cris Johnson, Gloria Downham, Sebastian Smelko,

1. The meeting was called to order at the Indiana Criminal Justice Institute by Chezem.

2. A motion was raised and passed by the board to recommend that Dr. Monforte 's contract be extended.

3 A motion was made and passed unanimously by the board that a referral for investigation of the loss of department property (Dr. Wagner's computer) be investigated and the findings of this investigation be reported to the board to assist in the development of protocols for security and confidential information.

4 Klaunig brought to the board's attention that it is apparent that the breath test program needs attention immediately. The rest of the board agreed. There was discussion about the selection of and reliability of the new breath test instruments (Intoximeters). The Board requested that the reliability of these instruments is confirmed by department of toxicology and the director of the department, that the instruments be examined to see if they conform to the standards and regulations set forth by the department of toxicology and the State of Indiana, that if the instruments do not conform to Indiana regulations, a re-biding of the breath test instruments be performed. Once the breath test instruments are selected it is important that promulgation of new rules be made. There was discussion about breath test training and recertification to insure that the training conforms to Indiana regulations. The Board urged that the currently used online recertification training be suspended and live instructor based recertification be reinstituted. The Board also strongly urged that regional recertification be reinstituted.

5. The organizational structure of ISDT was discussed and the duties and reporting lines for the director, chief toxicologist and an administrator be developed and incorporated into the org chart. Salaries of these individuals should be nationally competitive and a job posting for the director should be performed immediately.

6 The board continued to discuss the paperwork audit and additional concerns that the auditors were and are doing their work in isolation. The board recommended that a charge and protocol be developed for the audit that includes a third party to review the audit. The reporting of the audit results should include a clear scientific and lay definition of any problems found and accurate description of the severity of the problems be conveyed to the public in a proper manner. Retesting of samples that were identified by audit be performed by a nationally accredited laboratory (ISO 17025). NMS was suggested as a possible vendor for this task since they are already under contract with the state department of toxicology and are properly accredited. . The information provided indicates that the reviews of the alcohol testing have not begun. The board had many questions about the specific provisions of the contract as well as cost over runs and the actual review process. As a result of the fact finding and review by the board, the board recommends that the paper audit be put on hold (that the proposed blood alcohol paper audit not be initiated at this time) and that retesting of the samples identified as questionable in the paper audit for cocaine and THC be performed

7. The Board discussed the concerns and ideas of the department employees that were interviewed at the last meeting.

8. Public notice will be posted for the next meeting

9. Motion to Adjourn was made and passed

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Toxicology Advisory Board
Minutes

Date: July 15, 2011
Location: Indiana Criminal Justice Institute (ICJI).

Board Members Present: Mike Medler, Dr. James Klaunig, Linda Chezem

Other Attendees: Cris Johnson, Gloria Downham, Ryan Klitzsch, Sebastian Smelko,

1. The Toxicology Advisory Board meeting was held at the Indiana Criminal Justice Institute (ICJI).

2. Cris Johnston noted to the board that he, Sebastian Smelko, Assistant Counsel to the Governor, met with Jeff Linder and Joe Scodro from IU to further discuss the terms of a Memorandum of Understanding (MOU). The MOU is anticipated to be signed shortly.

3. Chezem recommended the Board should consider making a recommendation to Governor Daniels advising him that a person be appointed as acting director of the department of toxicology. Motion was made by Klaunig, and seconded by Mike Medler to approve recommending to the Governor to appoint an acting or interim director no longer than six (6) months, and that said director be given adequate supervision. Motion carried by consensus of the board.

4. The Board agreed that it should write an interim report to Governor Daniels and the report should reflect the information gathered in previous Toxicology Advisory Board meetings and what recommendations were made. Chezem volunteered to prepare an outline draft of the report to send to the Board for their review and recommendations.

5 Chezem discussed the confusion and misunderstandings from the paperwork audit. Mike Medler made a motion, and seconded by Klaunig, after reviewing the agreement for consulting services with Forensic Consultants, that the audit field work should be put on hold pending actual testing and retesting of the THC and Cocaine samples identified in paperwork audit that may have technical problems. It was noted by the board that the contract for digitizing the records for cases for the audit review only included QC at the vendor level. Motion carried by consensus of the board.

6 Mike Medler made a motion, and seconded by Jim Klaunig that the retesting be completed as soon as possible by an independent lab with a recommendation to send samples to NMS Lab, an accredited lab that currently has a contract with toxicology. Motion carried by consensus of the board.

7. A phone call during the board meeting was initiated by Mike Medler, to National Forensic Science Technology Center to speak with Kevin Lotheridge (CEO), David Epstein (Laboratory Director) and David Sylvester (Chief Projects Officer). Chairperson Chezem asked Mike Medler

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to chair this section of the meeting. Members of the board introduced themselves to the NFSTC personnel.

Discussion held by the members of the advisory board and nonmembers attending the meeting via phone call in relations to: conducting testing and retesting drug samples, appointing an interim director and the cost to hire outside laboratories. Recommended items suggested by the members and nonmembers and requesting advise on transitioning under the university to the state included

a. Time frame to put a quality (accredited) laboratory system in place

b. Importance of needs assessments of ISDT

c. Training component for the Breath testing program and breath testing instruments

d. Good Implementation plan

e. Clearing the back log samples of drug related cases

f. Recruiting an experienced Interim director appointed by the Governor from the outside to run a quality(accredited) laboratory system

g. Appoint an Administrator over the ISDT with experience in accredited forensic labs knowledge of labs

h. Appoint a Chief Forensic Toxicologist under the Administrator to conduct testimonies and validations and two other Toxicologists. One would oversee the blood alcohol program and one would oversee drug program combined and one would oversee the breath testing program with both reporting to the Chief Forensic Toxicologist

i. Understanding the law enforcement issues and stakeholders issues

j. Standalone state laboratory conducting blood alcohol testing and drugs

k. Teaching component for judges, prosecutors and lawyers in the state knowledgeable in forensic science by using the statute attached to the departments' responsibility to conduct the education/training for the criminal justice system

l. Hiring qualified forensic scientists

8. Chezem moved and was seconded by Jim Klaunig that the engagement of National Forensic Science Technology Center to conduct an evaluation of the management and forensic science programs of ISDT be executed as soon as possible. The first task order should be a needs assessment. Motion adopted by consensus of the board.

9. Mike Medler made a recommendation in response to a question from ISDT regarding laboratory instrumentation validation; the Board will advise the Governor's Office to ask the ISDT for additional information on their plans for the validation of lab instrumentation. Specifically, request a proposal detailing in writing how validations conducted by *Agilent* comply with ISO 17025 (general requirements needed for accreditation) standards why the validations are needed; what it will accomplish; who the vendor is; and what the vendor's specifications are in completing it under ISO 17025 (general requirements needed for accreditation).

10. Public notice will be posted again and each time that the Board meets.

11. Motion to Adjourn was made and passed

Toxicology Advisory Board
Minutes
August 19, 2011

Location: State Department of Toxicology

Board Members Present: Linda Chezem, Dr. James Klaunig & Mike Medler

Other Attendees: Larry Landes, Ed Zych, Ryan Klitsch, Debbie Reasoner, Dr. Scott Kriger and Gary Brackett

1. Minutes of previous minutes were distributed. Board members reviewed the minutes of the previous meetings and made corrections. Klaunig made a motion to approve the minutes as corrected. Medler seconded the motion. Motion unanimously approved. [Dr. Klaunig has the list of corrections and addendums.] Chezem expressed appreciation to Klaunig for preparing the minutes of the previous meetings.

2. Klitsch reported that the IU MOU is supposed to be finalized today. Klaunig made a motion that the Toxicology Advisory Board be provided with a copy of the MOU for informational purposes once it is completed and signed. Medler seconded the motion. Motion approved.

3. Kriger and Medler presented information on the paperwork audit and laboratory retesting of samples. Kriger reported that ISDT has retrieved case files from storage and approximately 500 cases have been identified that will need to be retested for THC and cocaine. Klaunig asked if a protocol has been written as to which cases will be tested. Krieger stated that all THC and cocaine cases identified by the audit with potential problems will be retested. The cost to retest at NMS labs will be $68.00 per test. The estimated cost to complete the retesting project is $33,469. Kriger questioned whether or not the NMS laboratory was acceptable to the Board. There was discussion as to the ASCLD accreditation of NMS in toxicology. NMS accreditation will be reviewed. Klaunig made a motion that the Toxicology Advisory Board reconfirm their recommendation to the Governor made in their interim report dated July 22, 2011, that the retesting be performed as quickly as possible. Medler seconded the motion. Motion was approved.

4. Klitzsch stated that he has nothing to report on the contract with the National Forensic Science Technology Center.

1. additional masters or doctoral level toxicologist position (Assistant/Associate Director) and a trainer position are needed to assist with the Breath Testing Program. The new Intoximeter breath test instruments need to be evaluated. Decisions need to be made as to whether one test or two tests are administered. An approved method will need to be established for the new instruments. Kriger reported that all Intoximeter instruments in storage now have a State of Indiana asset tag. Instruments will be moved from the current storage facility to a State owned environmentally controlled storage facility within the next 10 days once notification is sent to the current facility to terminate the existing contract. Discussion was held as to whether or not Dr. Kriger has the authority to hire an Assistant or Associate Director and a Trainer. Klitsch will ask for clarification from the Governor's Office.

2. Kriger reported that there is no longer a backlog of cases to be tested. The average turnaround time for blood alcohol testing is two weeks.

3. Klaunig asked Kriger who is handling legal requests. Kriger reported that Anna Hileman is handling requests for records and subpoenas. Kriger reported that Chris Johnston is talking with the Attorney General's office about assigning a specific attorney to work with ISDT on legal challenges. Klitsch will follow-up.

4. Chezem invited guests to share any comments or concerns. Both Landes and Zych emphasized their support for retesting the THC and cocaine cases as quickly as possible. Zych asked about officer training at the Breath Test Schools. Kriger reported that officers use simulator solutions to perform breath tests. Officers do not drink alcohol at the Schools. Landes, Zych and Reasoner shared their concerns about the reputation of the ISDT Lab. Toxicology Advisory Board members shared information about the National Forensic Science Technology Center and how they are an outside entity which reviews laboratories and works with them to make improvements to rebuild public confidence. A suggestion was made to consider changing the name of the laboratory.

5. Toxicology Advisory Board members agreed to postpone meeting again until the following information is available: 1) a copy of the signed IU MOU is available; 2) status of National Forensic Technology Center contract; 3) a report has been received from the Governor's Office on the status of the initial recommendations made in the July 22 Interim Report (attached to these minutes); and, 4) an attorney has been assigned by the Attorney General's office to work with ISDT on legal issues. Klitsch suggested that a representative from the Attorney General's office be invited to future Board meetings.

1. Klaunig reported that he suggested that Dr. Kriger consult with all interested parties (prosecutors, defense attorneys, judicial, law enforcement, etc.) once a decision is made to move forward with the Intoximeter instruments.

2. Motion to adjourn was made at 11:00 a.m. Motion passed.

Toxicology Advisory Board
Minutes
September 9, 2011

Location: State Department of Toxicology

Board Members Present: Linda Chezem, Dr. James Klaunig & Mike Medler

Other Attendees: Amy Summerfield, Melissa Garten, Stacy Uliana, Senator Tom Wyss, Mark McCordia, Cris Johnston, Gloria Downham, Ryan Klitzsch, Debbie Reasoner and Gary Brackett

1. Chezem convened the meeting and asked everyone to introduce themselves.

2. Minutes of August 19 meeting were distributed to Toxicology Advisory Board Members. Klaunig made a motion to approve the minutes as distributed. Medler seconded the motion. Motion unanimously approved.

3. Johnston provided an update from the Governor's Office on the status of the recommendations to the Governor by the Board. Recommendation #1 has been accomplished - Dr. Scott Kriger has been appointed Interim Director effective July 1, 2011 for a period of six months.

   Recommendation #3 is being implemented. The State Financial System has ISDT set up and is ready for the ISDT to transition from IU to the State. No money from the State appropriation has been distributed this fiscal year. Funds from April – June 2011 were reverted to the State on June 30, 2011. Fund account balances as of August 31, 2011 were presented: State Appropriation Account - $349,288; Tuition & Service Account - $1,382,329; Toxicology Lab Account - $76,510. Johnston noted that the ISDT State Appropriation Account fund balance will cover expenses for several months of FY2011 prior to drawing on that appropriation. The first two months of this fiscal year reflect lab fees paid to AIT and audit fees that will moderate in coming months but ongoing monitoring and forecasting will continue. ISDT maintains financial records on the IU School of Medical financial system under the MOU. Monthly spending reports are provided by Gary Brackett to the OMB.

   Over 270 ISDT assets have been tagged (including the Intoximeters) and logged into the State inventory system. Johnston noted that the Intoximeters and printers have been relocated to the ISDT facility from the non-climate controlled facility saving ISDT $675/month. The current BAC DataMasters will be tagged shortly. Senator Wyss asked about the process for implementing the Intoximeters. General discussion was held about the process for implementation (validation of instruments, training, input needed from stakeholders regarding the need for one or two breath tests, etc.).

The State Personnel Office has received job descriptions and information about benefits and is formulating a transition work plan. A meeting is set for Monday, September 12. Sebastian Smelko is conducting a search for a dedicated Associate General Counsel for ISDT. Senator Wyss questioned why the Attorney General Office's is not providing General Counsel for ISDT. Johnston stated that the Governor's Office believes that there is a need for a full-time Associate General Counsel for ISDT.

A working group including a team from the Indiana Office of Technology (IOT), Rob Lawson and Gary Brackett (ISDT) and Gloria Downham (OMB) are working through all the IT-related issues. Topics include: users/account management; databases; servers; website; disaster recovery; network/cabling/circuits; telephones; and HR and financial support systems. The Toxicology Advisory Board emphasized the need to have a security plan in place. Johnston reported that the State has security protocols.

Recommendation #5 – Johnston reported that a request was made to the Bureau of Justice to see if they would be willing to provide funding for the needs assessment of the ISDT by the National Forensic Science Technology Center (NFSTC). NFSTC is a 501(c)3 not-for-profit corporation that provides quality forensic services including training, assessment, research and technology assistance to the justice and forensic communities. Johnston reported that the Justice Bureau does not have funds available but that the Department of Administration has a special appropriation account that has agreed to fund the project. Johnston, Downham and Dr. Kriger met with representatives from NFSTC. NFSTC was asked to prepare a proposal refining the scope of the project for discussion and review. Senator Wyss asked about the status of a search for a permanent Director. Wyss expressed concern that the position not be a political appointee but someone who has the scientific background and qualifications of the position. Board Members stated that part of the NFSTC review would include a review of the current organization chart of ISDT. Board members have suggested that an administrative director be appointed and that a Chief Toxicologist be recruited to actually run the lab along with a couple of Assistant/Associate Toxicologists. The Board also recommends the implantation of a permanent Advisory Board. Chezem stated that the Board should be included in the discussions with representatives of NFSTC before a contract is signed. Board members asked about the timeframe for the assessment. Johnston reported that NFSTC stated the assessment could be completed in 4-6 weeks.

Recommendation #4 – Johnston reported that Dr. Klaunig has agreed to provide advice regarding the breath testing program. Dr. Kriger has provided the Board with a draft protocol to evaluate the Intoximeters. Once this evaluation is completed, an approved method will be drafted and feedback will be solicited from various stakeholders (prosecutors, law enforcement agencies, defense attorneys, etc.) so that IAC 260 can be

amended to provide for implementation of the new instruments. General discussion was held about whether or not one or two tests should be used. The DataMaster uses a single test.

Recommendation #2 – The paper audit was suspended until retesting of the problematic cases is conducted. Retesting will begin next week. Johnston reported that NMS is not an ISO 17025 certified laboratory. Medler made a motion to accept NMS Laboratory as a qualified laboratory to provide for the retesting of the samples. Klaunig seconded the motion. Motion unanimously approved. Senator Wyss asked that once the results are known that all parties review the data and put together a plan to publicize the information so that a unified communication is place. Johnston reported that new letters have been drafted to be sent to Prosecutor's Offices to inform them of the retesting procedure. The letters will be reviewed at the end of this meeting.

The Governor's Office has signed the MOU. The School of Medicine needs to sign the MOU. A meeting is set for next Tuesday with Jeff Linder and Joe Scodro. Johnston reported that he anticipates that the MOU will be fully executed at that meeting.

A question was asked as to whether or not Dr. Kriger has the authority to hire additional staff as needed. Board members agreed that Dr. Kriger has the authority to hire additional staff. Klaunig made a motion that Dr. Kriger be allowed to hire any additional staff needed and that positions be advertised through all professional organizations (SOFT, SOT, ASCLAD, etc.). Medler seconded the motion. Motion unanimously approved.

4. Klitzsch reported that the next Governor's Council Meeting on Impaired & Dangerous Driving is scheduled for Friday, September 16 at 12:30 p.m. in Government Center South. One of the agenda items will be an update on the status of the Indiana State Department of Toxicology. Chezem will present the Interim Report of the Board. A suggestion was made to invite Dr. Kriger to attend the meeting.

5. Board members acknowledged that sufficient notice was not given for today's meeting. Chezem asked Klitzsch to prepare a distribution list for meeting notifications which will include Dr. Kriger, Gary Brackett, Senator Wyss, Cris Johnston and Gloria Downham. Klitzsch noted that all meetings are posted on the Criminal Justice Institute website: www.in.gov/cji.

6. Board members noted that they would like to have the lab samples retested by the first of October, if possible. General discussion was held about whether or not the audit would continue. A decision will be made after reviewing the results of the retesting. Board members noted that retesting of blood for alcohol provides unique challenges in terms of sample denigration, specific blood alcohol level, etc.

7. Summerfield and Garten shared concerns that police officers are not recertifying as Breath Test Operators because they were waiting for the implementation of the Intoximeters. Agencies are concerned about having to pay for additional certifications. General discussion was held concerning the fact that training would need to be pro-rated or possibly waived in order to be fair to the police agencies.

8. The next meeting will be held on Friday, October 7 at 9:00 a.m. at the ISDT facility.

9. Medler made a motion to adjourn at 10:45 a.m. Klaunig seconded the motion. Motion passed.

Toxicology Advisory Board
Minutes
November 29, 2011

Location: State Department of Toxicology

Board Members Present: Linda Chezem, Dr. James Klaunig & Mike Medler

Other Attendees: David Powell, Chris Daniels, Jennifer Haley, David Wedding, Larry Landis, Amy Summerfield, Ryan Klitzsch, J.J. Paul, Tim Evens, Ed Zych, Terri Kendrick, Dr. Krieger, Mark (from Intoxilizers)

1. Judge Chezem convened the meeting and asked everyone to introduce themselves.

2. Judge Chezem asked to hold off on September 9th meeting minutes until the next meeting.

3. Judge Chezem asked Dr. Krieger to provide a general update.

4. Dr. Krieger noted that all BAC test results are coming back well within 10 days. He noted that drug results were being made available in about 3-4 weeks.

5. Judge Chezem asked that Dr. Klaunig Chair the new business portion of the meeting to seek public input on the breath testing procedures.

6. Dr. Klaunig opened up the floor asking for comment on the protocol for breath testing. Dr. Klaunig added that Mark from Intoxilizers can answer specific questions regarding the breath testing instrument.

7. Mark from Intoxilizers noted that they randomly selected six instruments and took them back to their office in St. Louis to test them. Testing on the dry gas simulators showed they were spot on. Mark also noted that the testing of the instruments using wet gas was spot on as well.

8. Dr. Klaunig looked for input on the 20 minute wait period that currently exists and if changes to it are needed. Amy Summerfield noted that case law has been established on the current application of the 20 minute rule. Larry Landis noted that the defense wants a reliable process that begins when the officer sits down with the suspected impaired driver and pushes a button to begin the 20 minute time at the instrument to begin a countdown.

9. Dr. Klaunig then moved on to ask for comments on the one test versus two tests on the instrument. Larry Landis noted that two tests brings more certainty. Mike from Intoxilizers noted that research has indicated that two tests are preferred. He went on to note however that 12-13 states currently use one test.

10. Dr. Klaunig noted that he has not heard any comments or concerns about the dry gas simulator.

11. Dr. Klaunig noted that written comments from attendees regarding the discussions from this meeting should be sent to Ryan Klitzsch for incorporation in the meeting minutes.

12. Judge Chezem noted that they next meeting will occur on December 9, 2011.

Toxicology Advisory Board Meeting Agenda

June 24, 2011

House Keeping

1. Review draft version of "charge" of the board (see document)
2. Develop a mission statement for the group, list goals and objectives for the department
3. Final review of MOU between State Budget and IU School of Medicine
4. Determine the point of contact for the Board at IU for requesting information

Items for Discussion/ to Request from IU

1. Request a budget review of toxicology from State Budget and ask what performance measures they expect to receive from IU or should the Board develop them.
2. Consultation with Dr. Glinn on audit, what are next steps on this?
3. Laboratory (drugs)
    a. Current (what is going on now)
        i. back log?
        ii. personnel
    b. Future (what is needed for the future and suspected timelines, finances required etc.)
    c. Past (the audit?) what is the contract with the auditors? who are they? what are they measuring ? is this the best way to perform the audit? should the audit also include the last three years ?
4. Blood alcohol testing
    a. current (what is going on now)
    b. back log?
    c. future (what is needed for the future and suspected timelines, finances required etc.)
    d. past (are they planning to audit this also ?)
5. Breath test program

a. current (what is going on now)

   i. training

   ii. instruments

   iii. personnel

   iv. back log?

b. future (what is needed for the future and suspected timelines, finances required etc.)(are the instruments acquired the best for Indiana?)

c. past (should we the panel audit this program for the past 5 years?) or at least perform a review? should we contract with someone for this? What is the status of this important program that seems to have been pushed to the background

2. Personnel

   a. current (what is going on now)(do we have CVs (resumes) and job descriptions for all? have employee evaluations been done on these people for the past 3-5 years

      i. what is the morale of the group

      ii. is there an org chart

   b. future (what is needed for the future?)

3. Training and Education

   a. What is occurring with the training of the courts, law enforcement, and prosecutors/defense attorneys for the past 5 years

   b. How about technical people in the lab and in the breath test program

4. The initial enabling statue for the department indicated research as a component. Does this continue or not?

   a. If yes, what are the proposed research projects and who is overseeing or will oversee? Is a statute change needed?

Future Items

1. Develop a monthly timeline of objectives for the next year.

1. Develop a strategic plan for the breath testing program that includes an evaluation of the instruments.
2. Survey and develop a project/plan to address the educational needs of the criminal justice system about the department and its work. Not to be limited by the breath test program.
3. Organization of the final report. What will it look like?

Toxicology Advisory Board Meeting Agenda

July 15, 2011

- Discussion on completing an interim report on the initial evaluation of ISDT
- Discussion on incoming and future invoices from Forensic Consultants
    1. Current PO is authorized up to $255,000, total invoices stand at $252,693.75 with additional invoices expected with Forensic Consultants continuing their work. What are next steps?
    2. If PO is increased, by how much and who has the authority to authorize the additional expense?
- Discussion on costs and need to have lab instrumentation validated independently as preparation for accreditation
- Discussion on who, if anyone, is being paid by ISDT to teach classes
- 10 am conference call with NFSTC (Kevin Lotheridge and David Sylvester) 866-910-4857 Pass code: 641146
- Timelines/ reports to draft
- Set next meeting

Toxicology Advisory Board Meeting Agenda

August 19, 2011, 9:00 a.m.

Indiana Forensic and Health Sciences Laboratory

- Review of previous Toxicology Advisory Board meeting minutes
- Board member report outs
    - Judge Chezem
    - Dr. Klaunig
    - Mr. Medler
- Additional items for discussion
- Set next meeting date if applicable

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Mitch Daniels, Governor

TOXICOLOGY ADVISORY BOARD
MEETING NOTICE

The Toxicology Advisory Board will hold a meeting on **Thursday, August 30, 2012**. The Board will meet at **10:00 a.m.** in the cafeteria room of the State Department of Toxicology located at the Indiana Forensic and Health Sciences Laboratory at 550 West 16th Street, Indianapolis, Indiana.

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TOXICOLOGY ADVISORY BOARD
MEETING NOTICE

Cancelled

The Toxicology Advisory Board will hold a meeting on **Friday, October 7, 2011**. The Board will meet from **9:00 a.m. until noon** at the State Department of Toxicology located at the **Indiana Forensic and Health Sciences Laboratory** at **550 West Sixteenth Street, Indianapolis, Indiana.**

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TOXICOLOGY ADVISORY BOARD
Executive Session Meeting Notice

An executive session of the Toxicology Advisory Board will be held on **Friday, October 21, 2011.** **The Board is meeting pursuant to IC 5-14-1.5-6.1(b)(2)-(5) and is meeting only in executive session.** The Toxicology Advisory Board will invite those persons (if any) to the executive session to answer questions or provide information. The Board will meet at **10:00 a.m.** at the State Department of Toxicology located at the Indiana Forensic and Health Sciences Laboratory at 550 West Sixteenth Street, Indianapolis, Indiana.

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TOXICOLOGY ADVISORY BOARD
Executive Session Meeting Notice

An executive session of the Toxicology Advisory Board will be held on **Tuesday, November 29, 2011.** **The Board is meeting pursuant to IC 5-14-1.5-6.1(b)(2)-(5) and is meeting only in executive session.** The Toxicology Advisory Board will invite those persons (if any) to the executive session to answer questions or provide information. The Board will meet at 8:30 a.m. in room 130 of the State Department of Toxicology located at the Indiana Forensic and Health Sciences Laboratory at 550 West Sixteenth Street, Indianapolis, Indiana.

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TOXICOLOGY ADVISORY BOARD
Executive Session Meeting Notice

An executive session of the Toxicology Advisory Board will be held on **Friday, December 9, 2011.** **The Board is meeting pursuant to IC 5-14-1.5-6.1(b)(2)-(5) and is meeting only in executive session.** The Toxicology Advisory Board will invite those persons (if any) to the executive session to answer questions or provide information. The Board will meet at 9:00 a.m. in the 11th floor conference room across from the Indiana Criminal Justice office located in the east tower of the PNC Center at 101 W. Washington St., Indianapolis, IN 46204.

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TOXICOLOGY ADVISORY BOARD
Executive Session Meeting Notice

An executive session of the Toxicology Advisory Board will be held on **Friday, May 4, 2012.** **The Board is meeting pursuant to IC 5-14-1.5-6.1(b)(2)-(5) and is meeting only in executive session.** The Toxicology Advisory Board will invite those persons (if any) to the executive session to answer questions or provide information. The Board will meet at 9:30 a.m. in the cafeteria room of the State Department of Toxicology located at the Indiana Forensic and Health Sciences Laboratory at 550 West 16th Street, Indianapolis, Indiana.

STATE OF INDIANA

Mitch Daniels, Governor

TOXICOLOGY ADVISORY BOARD
MEETING NOTICE

The Toxicology Advisory Board will hold a meeting on **Friday, May 4, 2012**. The Board will meet from **10:30 a.m. until noon** in the cafeteria room of the State Department of Toxicology located at the Indiana Forensic and Health Sciences Laboratory at 550 West 16th Street, Indianapolis, Indiana.

Proposed Agenda:

- Call to Order
- Approval of December 2011 Minutes
- Old Business
- Review of Board's Charge (*IC 10-20 and IC 5-14-6)*
- Transition Update
- Director's Report
- New Business
- Adjourn

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DRAFT

Needs Assessment of the Indiana State Department of Toxicology

Introduction/Purpose

The National Forensic Science Technology Center (NFSTC) was contracted by the Governor's Office of the State of Indiana to perform a needs assessment of the Indiana State Department of Toxicology (ISDT). Through legislative action, the ISDT became an independent stand-alone agency mandated to establish professional management systems as well as quality assurance programs capable of meeting international accreditation standards.

Contract specifications required an on-site review and evaluation including the organizational design of the laboratory to include operations, Breath Testing Program management, quality assurance and training and education. In addition, laboratory positions and their associated skill requirements would be assessed as they related to the laboratory's organizational structure. Finally, a review would be conducted regarding business practices and recommendations made related to resource optimization and workload management.

The project team consisted of extremely qualified NFSTC staff members and a toxicology contract subject matter expert assembled to meet the requirements of the contract. The needs assessment process included the analysis of laboratory documents and materials, on-site review and staff engagement. The format of this report includes general categorical areas reviewed with team observations and recommendations presented as well as a concluding section. The observations and corresponding recommendations are numbered for ease of review and understanding. However, no order of assigned importance is intended where more than one observation or recommendation is noted.

Laboratory Organization Design

Operations

Observations:

ISDT has followed a historical laboratory organizational structure that lacks the resources required to adequately develop, implement and document the complex activities of a stand-alone, fully functioning toxicology laboratory as well as operate a statewide Breath Testing Program. Although procedural, policy and documentation efforts must be noted, significant gaps and omissions exist. The complex management, quality and technical activities that occur in a forensic laboratory require adequate staffing and commitment. Several noted vacancies in key roles exist with the organizational structure of ISDT. In addition, the ISDT Director is presently spending considerable time outside the laboratory in courtroom testimony, which adversely

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affects the continuity of management and slows down the progress of implementing policies and processes.

Recommendations:

A new organizational structure that addresses the change in services that will be provided now and in the future by ISDT should be investigated. Putting a Laboratory Manager/Quality Coordinator in place to build and implement a comprehensive quality system as well as conduct the day-to-day business of the laboratory should be considered.

In addition, putting a Chief Toxicologist/Scientist or similarly titled individual in place could affect technical issues and provide for consultation with the Laboratory Manager/Quality Coordinator on procedural activities. This scientist would also increase legal support (litigation testimony) capacity that is anticipated. Such increased support often accompanies new agency operations and services as a result of precedent-setting adjudication challenges.

Addendum #1 depicts a proposed organizational chart for ISDT. This chart proposes two upper level management positions, one being a Chief Toxicologist/Scientist to handle all technical issues within the laboratory. The second position is designated as a Laboratory Manager/Quality Coordinator to handle the operational activities. The present Technical Consultant activities would transition to the Chief Toxicologist/Scientist position. The present vacant positions of Associate Director and Quality Manager would be combined to form the Laboratory Manager/Quality Coordinator position that would also have oversight over the Breath Testing Program. Evidence Technicians would also be moved to under the guidance of the Laboratory Manager as evidence reception, evidence handling and chain of custody are better suited under the guidance of a Laboratory Manager. The proposed chart also reconfigures and balances the span of control on the technical side concerning the number of Analysts, Senior Laboratory Assistants and Data Reviewer/Certifiers that report to the two projected analytical supervisors.

Breath Testing Program

Observations:

Efforts to implement a new Breath Testing Program to date have not been successful. It was reported to the project team that three (3) years ago a large investment of approximately 1.5 million dollars was made into new breath testing instrumentation. As of the date of the assessment, the new instrumentation is in storage and has not been deployed. The promulgation of rules and officer training and certification related to the new instrumentation has not been completed. It was also reported to the

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project team that there has been a significant decline in the number of certified breath test operators capable of performing qualified breath tests throughout the state.

Recommendations:

A full-time supervisor or coordinator for the Breath Testing Program needs to be put in place. This supervisor needs to be provided the authority to determine the approved breath testing method, enact the promulgation of the rules and insure quality assurance activities of the program. The supervisor would work to establish acceptable officer training and certification procedures. Finally, this individual could work to determine the most appropriate course of action to engage the previously purchased testing instrumentation, ensure its deployment throughout the state and set re-training and periodic re-validation program requirements.

Quality Assurance

Observations:

Although initial activities regarding the ISDT Quality Assurance Program have been started, the program is incomplete and fragmented. Many areas required of a quality assurance program are non-existent; one example is a corrective action process. There are procedures documented, such as the proficiency testing process, which make reference to a corrective action procedure; however, this process is not documented in any of the materials provided.

A quality assurance manual usually follows an informational pattern as related to a particular accreditation program. What this means is that accreditation programs have standards and criteria laid out in a particular order. For ease of accreditation review, a laboratory will usually implement a quality assurance manual that mirrors the pattern of the particular accreditation program. ISDT begins their quality manual with an Organization Structure Chart, Mission Statement and Quality Statement, which is appropriate. The next sections of the manual concentrate on areas such as pipette calibration and thermometer calibration, which normally would appear as standard operating procedures. ISDT does have several stand-alone operating procedures similar in nature to the pipette and thermometer calibration sections.

Some versions of the SOPs provided for review are either out-of-date or are missing implementation / effective date notations. Those noted:

- Elisa Blood Drug Screening
- Elisa Urine Drug Screening
- Analysis of Volatiles by Headspace GC

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Several SOPs documents are still utilizing the Indiana University School of Medicine header on the document as well as making reference to an ISO 17025 standard. Depending on the chosen accreditation program this standard information may not be applicable. Those noted:

- Opiate Confirmation Protocol
- Cannabinoids Confirmation Protocol
- Zolipidem Confirmation Protocol
- Volatiles Confirmation Protocol
- Volatiles Screen Analysis
- Analysis of Volatiles by Headspace GC

Documented lab compliance with its SOPs would be measured by the accrediting agency using such implementation dates for SOPs that are in force on the date the accreditation application is ultimately made. Consistency in document format and content is also advisable.

Please see **Addendum #2** Quality System Review for further detailed information related to accreditation standards and ISDT compliance.

Recommendations:

A complete review of the Quality Assurance Program should be conducted to identify gaps in the program. Accreditation requires policies and procedures to be in place that meet applicable standards and/or criteria. Extensive documentation is an integral component of any accreditation program. Quality assurance documentation demonstrates that the laboratory in fact has a procedure and/or policy in place that meets the applicable standard or criterion and that the laboratory can demonstrate compliance with their own procedure or policy.

The management of ISDT should immediately analyze and determine the specific accreditation program from which they will seek to achieve accreditation. They should review all aspects of their quality assurance system and documentation to determine the gaps and omissions that would prevent them from achieving accreditation from the chosen program. Identifying an accreditation program will provide direction as appropriate quality system information and documentation continues to be developed.

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Laboratory Organizational Structure

Job Descriptions/Classifications

Observations:

The job descriptions provided are all listed under the IUPUI classification system. The duties and responsibilities as well as educational requirements of the positions generally follow stipulations recognized in the field. However, the job descriptions specifically for the analyst positions were very inconsistent in the wording of their requirements. For example, a Toxicology Analyst II is required to "perform qualitative and quantitative data analysis", but this terminology does not exist in either the Toxicology Analyst I or Toxicology Analyst III descriptions.

A review of the organizational chart revealed that many of the provided job descriptions as titled are not listed on this chart (Assistant Business Manager, Toxicology Laboratory Manager, Office Coordinator, Operations Manager, and Data Reviewer). In addition, many job positions listed on the organizational chart do not have accompanying job descriptions (Director, Technology Consultant, Business Manager, Executive Assistant Paralegal Office Manager, and Supervisor).

Upon reviewing the résumés provided for staff, all staff members meet the educational requirements of their positions with the exception of one analyst.

Recommendations:

The Assessment Team reviewed provided Indiana State Police Laboratory Forensic Scientist job descriptions. It is believed that the responsibilities, duties, job requirements and essential functions as listed in the ISP descriptions are in alignment with scientific activities occurring in ISDT. An analysis should be performed involving state personnel as well as the ISDT Interim Director to ascertain if any significant discrepancies exist between forensic toxicology laboratory positions versus those positions in ISP that require similar training, education and analytical capabilities. The proposed ISDT positions of Laboratory Manager/Quality Coordinator, Chief Toxicologist/Scientist as well as the present Evidence Technician can also be reviewed and brought into alignment with very similar existing job classifications of the Indiana State Police Laboratory.

The organizational chart for ISDT and associated job descriptions should be reviewed to ensure the positions on the chart are correct, that job descriptions for all positions listed on the organizational chart are in place and that all position titles are correct.

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All educational and experience requirements listed in the job descriptions should be reviewed to ensure consistency and appropriateness. Determination and decisions should be made on compliance with the job description requirements for staff presently in place.

Training and Education

Observations:

ISDT provided copies of specific training protocols. Several of these protocols contain a checklist to be utilized for documentation purposes upon completion of training activities. Five (5) protocols (amphetamine, barbiturate, cocaine, methadone, and opiate) did not contain a checklist that could be utilized for training completion documentation purposes.

Some employee training files contained a memorandum authorizing them to perform a certain type of testing activity. The provided employee training files, however, did not contain a checklist that documented the completion of the particular training protocol for which they were authorized to perform testing.

Recommendations:

As a mechanism of the Quality Assurance System, a documented training program should be established that contains specific components and requirements for documentation. All training protocols should be a part of this system as well as all checklists utilized to demonstrate completion of some or all elements of the training program.

Employee training files should be reviewed for gaps in documentation on training completed. All files should be updated with the proper checklist if specific training protocols have been completed.

Resource Optimization

Best Practices

Observations:

ISDT currently has two outsourcing contracts with private laboratories. One contract is with National Medical Services (NMS-Labs) and the second is with the American Institute of Toxicology (AIT). The project team was advised that outsourcing to AIT was no longer occurring. Metrics on the number and type of cases presently outsourced were not provided.

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Recommendations:

Data on the type and number of cases currently being outsourced should be compiled. An analysis should be performed regarding current ISDT testing scope and capacity and decisions made regarding outsourced testing versus in-house testing going forward.

Comprehensive compilations of specific legal and procedural challenges to outsourced test reports should be employed to guide resource allocation for staffing, training, test prioritization and potential continued outsourcing.

Workload Management

Observations:

The laboratory recently implemented a Laboratory Information Management System (LIMS). Statistical data capture for performance management began with the implementation of the LIMS program in approximately October of 2011. No historical data was entered into the system. It was indicated that performance metrics such as cases received, cases worked, analyst's workload, etc., prior to the implementation of the LIMS would be extremely difficult to retrieve.

A statistical breakdown on the type of case requests received was not available. It was conveyed that analysts perform assays on the type(s) of cases for which they have completed training. However, it is not readily evident what type of testing each analyst is qualified to perform. Presently performance metrics for individual analyst are not in place.

Recommendations:

ISDT should ensure that mechanisms are in place to immediately and comprehensively capture performance metric data. This data should include:

- Cases received by type
- Cases worked by type
- Cases backlogged by type
- Number of cases requiring court testimony
- Cases worked by analyst by type
- Number of cases outsourced by type
- Number of breath alcohol tests performed

Individual analyst testing capabilities should be identified and documented. Performance metrics for analysts should be initiated and documented.

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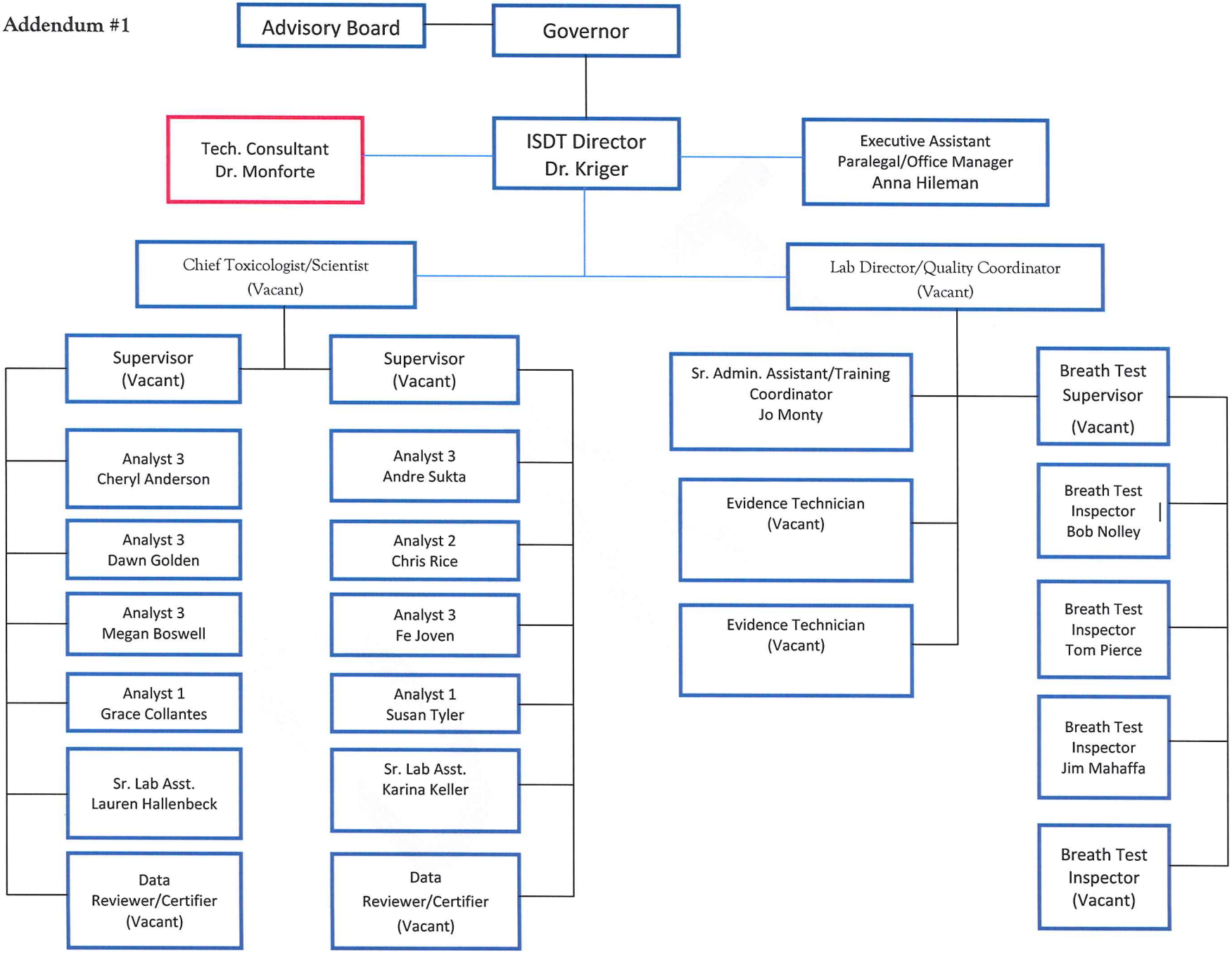
Conclusion

Since becoming a stand-alone entity, the management of ISDT has undertaken numerous procedural and quality assurance initiatives. Given the limited staff resources available, their efforts have not gone unnoticed. The gaps and omissions noted above are correctable, but will require commitment, resources and time. Having the right staff in place and completely focused on quality assurance system objectives, procedural documentation and technical activities is imperative. The State's commitment for ISDT to achieve accreditation status as well as regain professional credibility requires resources and staff dedication to these objectives, but they are achievable. The accreditation process is arduous, time-consuming and at times frustrating. The citizens of the State of Indiana as well as the customers of the ISDT expect professional, credible services to be provided and should expect nothing less.

Addendum #1



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Addendum #2

Quality System Addendum

Laboratory quality systems are built with documents and materials utilize to demonstrate compliance with established standards. This documentation includes a quality manual, policies, procedures, checklists and other forms that are used to address and fully demonstrate how the laboratory meets standards. The ISDT Laboratory Management has indicated they will seek one of two accreditation programs, the American Board of Forensic Toxicology (ABFT) Accreditation Program or the International Standards Organization (ISO) 17025 Accreditation Program.

For the purposes of this quality system addendum both accreditation programs are presented below with comments regarding the content of the ISDT quality system to comply with the essential accreditation standards. The scope of the contract and the hours allotted does not allow for a comprehensive and complete assessment of all of ISDT quality system materials.

American Board of Forensic Toxicology (ABFT)

Accreditation Manual (essential standards)

The ABFT Accreditation Program contains fourteen (14) sections with one hundred and thirty nine (139) standards. Each section contains standards in categories titled Essential (E), Important (I), and Desirable (D) with a laboratory only having to meet the essential standards to achieve accreditation. For the purpose of this review only the **Essential** criteria are presented with comments in *italics.*

Section A: Management and Administration

A-1 E Does the laboratory have a written statement of its mission or objectives?

> *The ISDT Laboratory Quality Manual contains a quality statement, mission statement and laboratory objectives.*

Section B: Personnel

B-1 E Does the laboratory have a Director with the required experience and qualifications?

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The Laboratory Director does possess the necessary qualifications and experience required by this standard.

B-3 Is the Director responsible for

a) E daily management of the laboratory?
b) E preparation and revision of the standard operating procedure manual?
c) E establishing procedures for validating new assays?
d) E maintaining a quality assurance program?
e) E training laboratory staff?

It can be inferred that the Laboratory Director has responsibility for these activities however the laboratory does not have documentation that clearly and concisely outlines the duties and responsibilities of the Director.

B-5 E Are the personnel trained appropriately?

It was observed by the Assessment Team that analytical personnel are operationally capable of performing appropriate testing activities. However, the documentation related to training programs and the successful completion of the training activities by analysts is lacking.

Section C: Standard Operating Procedure Manual

C-1 E Does the laboratory have a Standard Operating Procedure manual (SOP) which includes procedures for the routinely used analytical methodologies?

The laboratory currently has Standard Operating Procedures in place. All procedures are not in a manual per se and in fact all are not kept within the same electronic file. Some procedures are contained with the quality manual while others are stand alone documents.

C-2 E Does the SOP contain a list of analytes that are routinely quantitated?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

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C-3 E Is the list of routinely quantitated analytes consistent with the laboratory's stated mission?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

C-6 E Are the screening methods used appropriate for the laboratory's stated mission?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

C-7 E Has the Laboratory Director reviewed, dated and signed each procedure?

The alcohol-related methods, sample interpretation procedures, Analytical Figures of Merit (AFOMs; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), validation and batch acceptance specifications, and personnel training / certification documentation requirements all seem to be in place. On the other hand, many of the drug confirmation methods for blood, urine and other sample matrices are either not documented in current form, not signed in as the accepted versions, or staff training records are not available demonstrating the version of the method for which they were trained.

C-9 E Is there documented evidence of review of the SOP by the Director at least annually?

Several of the SOPs contain an approval and review date along with an area for the Director's signature. The copies of the documents provided to the Assessment Team contain dates of review and/or approval but do not contain a signature. The laboratory does not have in writing a documented process to follow regarding the review and approval of SOPs.

C-12 Does the SOP contain sections on:

a) E specimen receiving, accessioning, aliquoting and storage?

e) E copies of the routinely used analytical methodologies

f) E description of the quality assurance and quality control program?

g) E criteria for the acceptance of analytical data?

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The laboratory does have several SOPs in place. The Assessment Team did not observe a document describing the quality assurance and quality control program.

C-13 E Do the assay protocols in the SOP contains sufficient detail to allow the analyst to perform the assay?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

C-14 Where appropriate, does each of the analytical methods contain sections describing:

b) E details for the preparation of reagents, standards, calibrators and controls?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

Section D: Specimens, Security and Chain of Custody

D-2 E Does the laboratory compare the information on the labels against that on the requisition and document any discrepancies?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

D-3 E Does the laboratory assign identification number(s) to the specimens received?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

D-5 E Is entry to the laboratory controlled during working hours?

It was observed by the Assessment Team that access to the laboratory is controlled at all times.

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D-6 E Is the laboratory secure during non-working hours?

It was observed by the Assessment Team that access to the laboratory is controlled at all times.

D-7 E Does the laboratory secure short and long term specimen storage areas when not in use?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

Section E: Quality Assurance and Quality Control

E-1 E Is a suitably qualified individual assigned day-to-day responsibility for QA/QC?

The position of Quality Manager is currently vacant at ISDT.

E-3 E For *qualitative* assays does the laboratory include appropriate positive and negative controls with each batch of specimens for analysis?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

E-4 E For qualitative assays, are the results of these controls available for review?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

E-5 E Does the laboratory have written criteria for the acceptance of the qualitative controls?

The alcohol / volatiles procedures detailing QC acceptance requirements are well documented, have been implemented with all applicable staff, and appear to be in effect for current daily practice. However, efforts are needed to bring all drug testing procedures into the same compliance line with this accreditation standard.

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E-7 E For *quantitative* assays of common analytes, does the laboratory include appropriate controls with each batch of specimens for analysis?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

E-8 E Are the results of these controls available for review?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

E-9 E For quantitative controls, does the laboratory have written criteria for their acceptance?

The Assessment team did not observe documentation that summarized these criteria for drugs. It is possible that such a document exists, but on-site time may have been insufficient to close this potential criterion shortcoming.

E-11 E If the laboratory prepares its own calibrators and controls, are these made using independently prepared stock drug solutions?

The standard is not applicable to the laboratory.

E-14 E Does the laboratory take corrective action when control results exceed specified limits?

The Assessment Team observed instances of corrective action being implemented in testing activities. However, the laboratory is lacking a documented corrective action process and policy. While staff discussed corrective actions commonly employed for controls outside of limit, the specific actions were not documented in a cohesive manner, and did not follow a consistent, specified action plan.

E-15 E Is this corrective action documented?

The Assessment Team observed instances of corrective action being implemented in testing activities. However the laboratory is lacking a documented corrective action process and a centralized location for the

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logging for corrective action activities. Acceptance criteria are not fully documented and in final approved status. The specimen-to-specimen, batch-to-batch corrective actions were not systematically documented.

E-17 E Are proficiency test results reviewed by the laboratory director?

The ISDT Quality Manual stipulates that proficiency test results will be reviewed by the Quality Manager. The manual requires that the corrective action process be initiated and conducted by the Quality Manager for all incorrect proficiency test results. ISDT does not have a corrective action procedure or process in place nor does the quality manual articulate the Laboratory Director's involvement in the proficiency testing process.

E-18 E If unacceptable results occurred in PT programs did the laboratory take corrective action?

The ISDT Laboratory presently does not have a corrective action process and procedure in place.

E-19 E Was the corrective action for unacceptable PT results appropriate?

The ISDT Laboratory presently does not have a corrective action process and procedure in place.

Section F: Immunoassays

F-3 E If the immunoassay is being used to test specimens for which the assay is not approved by the manufacturer, or if the test method recommended by the kit manufacturer has been modified, has the laboratory validated these changes?

The Assessment team did not observe documentation related to this standard.

Section G: Chromotography, Mass Spectrometry, and Spectrophotometry

G-1 E Are the analytical protocols used for the chromatography based assays appropriate?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

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G-3 E For qualitative and quantitative assays, does the laboratory analyze calibrators and/or controls with each batch of specimens?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-4 E Does the laboratory analyze calibrators and controls in the same manner as unknowns?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-5 E Does the laboratory establish a valid calibration for each quantitative assay?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-6 E If the laboratory uses historical calibration for an assay, are calibrators and/or controls run with each batch of specimens for analysis to check stability of the calibration?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

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G-7 E Are appropriate criteria established for the acceptability of calibration data?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-9 E Does the laboratory use an appropriate internal standard for quantitative analysis?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-10 E For qualitative and quantitative assays, does the laboratory check for carry-over and contamination?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-12 E Are validation records maintained?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-13 E Does the laboratory maintain records of testing data including laboratory accession numbers, specimen type, analyst and date of analysis?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director

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acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-14 E Are the criteria for designating qualitative results as positive appropriate?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

G-15 E Where practical, are all reported positives confirmed by a technique based on a different chemical principle from the first test?

Documentation needs to be harmonized, with full supporting validation data for all AFOMs (Analytical Figures of Merit; e.g. sensitivity, selectivity, linear range, freedom from matrix interference), updated Director acceptance signatures and dates, staff training records, and specimen / batch documented compliance with these analytical criteria.

Section I: Thin Layer Chromatography

I-3 E Are standards applied to each thin layer chromatographic plate?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

Section L: GC/MS and Liquid Chromotography-Mass Spectrometry (LC/MS)

L-3 E Does the laboratory have written criteria for acceptable mass spectrometric tuning?

The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

L-6 E If the laboratory uses selected ion monitoring for identification, does it compare ion ratios and retention times between calibrators, controls and unknowns?

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The Assessment Team observed that the laboratory meets the standard in their documentation as well as operationally.

Section N: Safety

N-1 E Does the laboratory follow good laboratory safety practices?

It was observed by the Assessment Team that the laboratory staff does follow good safety practices.

N-2 E Does the laboratory have a safety manual which clearly defines all safety policies?

It was reported that the laboratory follows the IU School of Medicine Safety Manual. ISDT does not presently have its own safety manual in place or conduct and document its own internal safety training.

International Standards Organization (ISO) 17025

Accreditation Manual

The ISO17025 Accreditation Program contains two (2) primary sections, Management and Technical with twenty five (25) sub-sections containing a total of one hundred and twenty four (124) individual standards. All standards are essential for a laboratory to achieve ISO 17025 accreditation.

Section 4: Management Requirements

Sub-Section 4.1: Organization and Management

The standard requires that the laboratory possess documentation that establishes it as a legal entity which would require a copy of the legislative enactment to be present. The standard also contains several sections which require documentation of staff authority to conduct laboratory activities, communication policies to be in place and a clearly defined and articulated management/supervision structure. Documentation related to this standard is lacking.

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Sub-Section 4.2: Management System

This standard requires that the laboratory establish and document its' policies, systems, programs and procedures to assure the quality of testing. The standard stipulates that a quality system is required to contain or make reference to all of its components. With the absence of quality requirements such as a corrective action process, components of a complete quality system are lacking.

Sub-Section 4.3: Document Control

This standard requires that there be a master list of all documents, forms and or checklist that comprise the quality system. Other sections of the standard require a process for document identification, approval and document changes. ISDT does not have adequate information in place to demonstrate compliance with this standard.

Sub-Section 4.4: Review of Requests, Tenders and Contracts

The standard requires that the laboratory have a process for the review of testing requests. ISDT does have a testing process in place which meets the majority of the requirements of the standard with the exception of subcontracting testing activities.

Sub-Section 4.5: Subcontracting of Test and Calibrations

The standard requires that whenever a laboratory subcontracts testing activities to another entity, the laboratory must notify and gain approval from its customers regarding the subcontracting work. ISDT does not presently have a procedure that could demonstrate compliance.

Sub-Section 4.6: Purchasing Services and Supplies

The standard requires that the laboratory have a policy and procedure for the purchase of services and supplies. In addition the standard requires procedures for the reception and insuring of all critical consumables. It is assumed that ISDT would fall under State procurement rules and procedures. They would be required to possess information related to the State procurement process. As well documented procedures related to the reception, evaluation and verification of critical materials such as reagents is not in place.

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Sub-Section 4.7: Service to the Customer

The standard requires that the laboratory have a procedure and mechanism for obtaining feedback from their clients. ISDT does not have a procedure in place to comply with this standard.

Sub-Section 4.8: Complaints

The standard requires that the laboratory have a procedure in place to receive and resolve complaints related to their activities. The laboratory must also maintain records related to all complaints and the action taken. ISDT does not presently have a procedure in place to address complaints received.

Sub-Section 4.9: Control of Non-Conforming Tests

The standard requires that a laboratory have a policy and procedure to be implemented when testing activities do not conform to acceptable standards. It was observed by the Assessment Team that operationally the laboratory did correct nonconforming activities; however their process for identifying and implementing these correction activities was not appropriately documented.

Sub-Section 4.10: Improvement

The standard requires that the laboratory have a process for monitoring and potentially improving all aspects of their management system. ISDT does not presently have a documented procedure for the review of their management system.

Sub-Section 4.11: Corrective Action

The standard requires that the laboratory establish corrective action policies and procedures related to testing activities as well as other quality system and management operations. The corrective action policy and procedure must be very detailed and the standard requires very specific activities that must be included in the process. ISDT presently does not have a documented corrective action process in place.

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Sub-Section 4.12: Preventive Action

The standard requires that the laboratory constantly monitor all aspects of their quality system and where possible identify nonconformities and/or opportunities for improvement to the system. Because ISDT is in the early stages of quality system development they have not developed preventive action processes.

Sub-Section 4.13: Control of Records

The standard requires that the laboratory establish a procedure for the control of all quality system as well as technical records. ISDT does have a SOP that meets some requirements of the standard. The procedure in place would require modification to address further the identification of records, definition of archived records, and stipulations of retention time for all records.

Sub-Section 4.14: Internal Audits

The standard requires that the laboratory periodically conduct an internal audit of all of its activities. This audit is utilized as a tool to verify that the laboratory is continuing to comply with its' own policies and procedures as well as accreditation standards. Internal auditing is an integral component of any laboratory quality assurance system. ISDT has not developed a policy or procedure related to internal auditing.

Sub-Section 4.15: Management Reviews

The standard requires that the laboratory periodically conduct a review of their management system and activities. Similar to an internal audit, this review is utilized to insure that the laboratory management system is suitable and effective. ISDT presently does not have a policy or procedure related to the conducting of a management review.

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Section 5: Technical Requirements

Sub-Section 5.1: General

The standard requires the laboratory to develop methods, implement training programs and utilize equipment that considers uncertainty of measurement in their testing activities. It was observed that operationally ISDT does allow for uncertainty of measurement factors however some of their documentation does not specifically address their process for realizing the factors.

Sub-Section 5.2: Personnel

The standard requires that the laboratory insure the competency of all personnel involved in the testing process. This is achieved through demonstration of appropriate training program implementation, records of training completion by analyst, up-to-date and accurate job descriptions and records of analyst authorizations to perform testing. The records and documentation maintained by ISDT are incomplete and would not meet all of the requirements of this standard.

Sub-Section 5.3: Accommodation and Environmental Conditions

The ISDT does meet the requirements of this standard.

Sub-Section 5.4: Test Methods and Methods Validation

It was observed by the Assessment Team that the actual analytical testing activities and methods employed by the laboratory meet the requirements of the standard. However the documentation depicting these analytical activities and methods would not meet the requirements of the standard.

Sub-Section 5.5: Equipment

The standard requires that the laboratory have a documented process for the identification, listing, verification and maintenance of all equipment utilized in analytical testing activities. The ISDT laboratory does not have a documented process or listing of equipment demonstrate compliance with the requirements of the standard.

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Sub-Section 5.6: Measurement Traceability

It was observed by the Assessment Team that the laboratory has in place documentation and procedures which indicates compliance with the requirements of this standard.

Sub-Section 5.7: Sampling

It was observed by the Assessment Team that the laboratory has in place documentation and procedures which indicates compliance with the requirements of this standard.

Sub-Section 5.8: Handling of Test Items

It was observed by the Assessment Team that the laboratory has in place and follows documented procedures for the handling of test items.

Sub-Section 5.9: Assuring the Quality of Tests Results

It was observed by the Assessment Team that operationally the laboratory does assure the quality of testing results through data review and verification. Their procedure for this test assurance requires enhancing.

Sub-Section 5.10: Reporting the Results

The Assessment Team observed testing result reports currently generated by the laboratory. The content of the reports is appropriate and meets the requirements of the standard. However, ISDT currently does not have a policy or procedure in place outlining the requirements and methodology for the development and completion of these testing result reports.