

# ISO 17020 ACCREDITATION & NAME ACCREDITATION

OUR EXPERIENCE AND REMOVING THE MISCONCEPTIONS

- Barbara C. Wolf, M.D., Districts 5 & 24 Medical Examiner's Office, FL
- Sally S. Aiken, M.D., Spokane County Medical Examiner's Office, WA
- Amy C. Gruszecki, D.O., American Forensics, Mesquite, TX
- Ponni Arunkumar, M.D., Cook County Medical Examiner's Office, IL
- Roger A. Mitchell, Jr., M.D., Office of the Chief Medical Examiner, Washington, DC



# ISO 17020 ACCREDITATION & NAME ACCREDITATION

Where we are and how we got here

Barbara C. Wolf, M.D., Districts 5 & 24 Medical Examiner's Office, FL



## THE EARLY DAYS

- 1976: First NAME Accreditation certificates awarded
- 1977: Inspection and Accreditation became a NAME program.
- 2009: Annual inspector training was instituted.

# FIRST NAME CORE INSPECTION



SAINT LOUIS UNIVERSITY SCHOOL OF MEDICINE  
**FORENSIC & ENVIRONMENTAL PATHOLOGY**

GEORGE E. GANTNER, M.D.  
Professor & Chairman

December 1, 1975

Ali Z. Hameli, M.D.  
Secretary  
National Association of  
Medical Examiners  
200 So. Adams St.  
Wilmington, Del. 19801

Dear Dr. Hameli,

As previously arranged I performed a complete Medicolegal System inspection on November 19, 1975 on the "Office of the Chief Medical Investigator" of the State of New Mexico. The official address is:

James Weston, M.D.  
Chief Medical Investigator  
School of Medicine  
University of New Mexico  
Albuquerque, N.M. 87131

The host group provided me with a complete statistical tabulation of their office activities and a completed check list as described in the official inspection guidelines as published by the N.A.M.E. I have provided you with one set of these documents for archival purposes. I found the office to be operating well within the standards as established by N.A.M.E. in all particulars. Based upon my inspection and their compliance with all requirements I recommend approval of this system for the full specified period.

Sincerely,

*George E. Gantner M.D.*  
George E. Gantner, M.D.  
Professor Forensic & Environmental  
Pathology  
St. Louis University Medical School  
Chief Medical Examiner  
St. Louis County, Missouri

cc: Joseph Davis M.D., President, NAME  
Frank Cleveland M.D., Vice-President, NAME  
Leslie Lukash M.D., Chairman, Standards Committee  
James Weston, M.D.



NATIONAL ASSOCIATION OF MEDICAL EXAMINERS

200 South Adams Street Wilmington, Delaware 19801 Telephone (302) 571-3420

September 20, 1976

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Miami, Florida 33136

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Washington, D. C.

James T. Weston, M.D.  
Chief Medical Investigator  
Office of the Chief Medical  
Investigator  
University of New Mexico  
School of Medicine  
Albuquerque, New Mexico 87131

Dear Jim:

It is with great pleasure that I forward to your Office a certificate of accreditation of your Medicolegal Institute.

It is my hope that this program of Inspection and Accreditation will serve to upgrade the quality of Official Investigation of Death throughout the country.

Warm personal regards.

Sincerely yours,

*A.Z.H.*  
Ali Z. Hameli, M.D.  
Secretary-Treasurer

AZH:sjf  
Enclosure

cc: Leslie Lukash, M.D.  
Joseph H. Davis, M.D.  
Frank P. Cleveland, M.D.

THE UNIVERSITY OF NEW MEXICO

ALBUQUERQUE, NEW MEXICO 87131

Area Code 505

Phone 277-2036

PURCHASE ORDER

PURCHASE ORDER NUMBER .5 05039

TO: National Association of Medical Examiners  
200 South Adams Street  
Wilmington, Delaware 19801

SHIP TO ADDRESS BELOW

THE UNIVERSITY OF NEW MEXICO  
School of Medicine  
Shipping & Receiving  
915 Stanford N.E.

Mark for: Medical Investigator

ALBUQUERQUE, NEW MEXICO 87131

DATE \* 4/22/75 \* ACCOUNT NUMBER \* 087-530-020 \* DEPARTMENT \* Medical Investigator/Larrichio \* CHARGE FISCAL YEAR ENDING \* REQUISITION NUMBER \* M19033

PLEASE PROVIDE THE FOLLOWING:

PRICE EXTENSION

Payment to the National Association of Medical Examiners for inspection accreditation of the medicolegal investigative system.

100.00

1/26/76

Gentlemen:

The inspection of the New Mexico system has been completed and we request now the remittance of \$100.00 be submitted to this Office as soon as possible.

Thank you for your kind consideration.

*Ali Z. Hameli, M.D.*  
Ali Z. Hameli, M.D.  
Secretary-Treasurer

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THE UNIVERSITY OF NEW MEXICO

INSTRUCTIONS  
1. ACKNOWLEDGE ORDER, ADVISE OF SHIPPING DATE, AND MAIL ALL INVOICES TO U.N.M. COMPTROLLER'S OFFICE.  
2. PURCHASE ORDER NUMBER MUST BE ON ALL INVOICES.  
3. SUBMIT ORIGINAL INVOICE.  
4. SUBMIT SEPARATE INVOICE FOR EACH PURCHASE ORDER NUMBER.

*Frank M. ...*  
PURCHASING AGENT

13A PROFESSIONAL CREDENTIALS AND PRIVILEGES

13A.1 Is licensure of the medical staff verified at the time of initial employment? II ✓ — —

13A.2 Does the chief medical examiner evaluate the performance of each member of the professional staff at least once each year? I ✓ — —

13B TRAINING AND CONTINUING EDUCATION

13B.1 Are all new personnel provided information on the written policies of the office during orientation? II ✓ — —

13B.2 Is each licensed professional employee required to participate in continuing education? \* II ✓ — —

13B.3 Is there continuing education available for all medical investigators? I ✓ — —

13B.4 Are operators of radiologic equipment properly trained? I — — ✓

\* Not required under NY State Law. Staff required to list <sup>4.0</sup> hours of CME every 2 years.

## NAME ACCREDITED OFFICES

- Number of accredited offices as of August, 2019:
  - 83 Fully Accredited
  - 9 Provisionally Accredited
- The population now served by NAME accredited offices is approximately 149,857,097.



**BLUE=FULL**  
**RED=PROVISIONAL**

# INTERNATIONAL OUTREACH PROGRAM

- 2005: Forensic Medicine Division of the Health Sciences Authority in the Republic of Singapore becomes first international office to be accredited by NAME.
- The I & A Committee will continue partnering with the International Relations Committee to further the NAME accreditation process on the international level.

## ISO/IEC 17020 PROGRAM

- 2016: NAME entered into an agreement with ANSI-ASQ National Accreditation Board (ANAB) to develop an ISO/IEC 17020 program for medical examiner/coroner offices that seek ISO (International Organization for Standardization) accreditation, either solely or in addition to accreditation under the NAME Core program
- Ad hoc ISO Transition Committee organized to develop sample policies aimed at ISO/IEC 17020 requirements to assist offices seeking to apply for ISO accreditation

## ANAB/NAME JOINT ACCREDITATIONS

- January, 2019: American Forensics, Mesquite, TX becomes first office to undergo re-accreditation inspection under the NAME Autopsy Services program jointly with assessment under ISO/IEC Standard 17020
- March, 2019: Office of the Medical Examiner of Cook County, Chicago, IL underwent inspection for re-accreditation under the NAME core accreditation program jointly with assessment under ISO/IEC Standard 17020, as well as under Standard 17025 for forensic toxicology.

# THE FUTURE:



Everything that's old is new again.

# ISO 17020 ACCREDITATION AND NAME ACCREDITATION

Sally S. Aiken, MD

Spokane County Medical Examiner's Office

# ISO (EQUALS)

- Founded 1947  
(72 years)
- 21,740 standards  
to date



International  
Organization for  
Standardization

## NAME RELEVANT STANDARDS

- 9001 Quality management
- 15189 Medical Laboratories—requirements for quality and competence
- 17020 Conformity Assessment Requirements for the operation of various types of bodies performing inspections
- 17025 General requirements for the competence of testing and calibration laboratories

## ISO NUMBERS?

**ISO** Translated  
into Plain English

- 16982 Ergonomics of human-system interaction-usability methods supporting human-centered design
- **17020** Conformity assessment requirements for the operation of various types of bodies performing inspections
- **17025** General requirements for the competence of testing and calibration laboratories
- 17047 Application of Braille on signage, equipment, and appliances
- 17075 Leather-Chemical determination of chromium (VI) content in leather

## OF 21,740 ISO CHOICES, WHY ISO 17020?

- No ISO standard is specific to Medical Examiners/Coroners
- ISO standards tend to be general, large organizations don't want to develop quality management systems for each department/function
- Developing a new ISO standards takes years, and begins with demonstration of a “market need”.

## ISO STANDARDS IN PLAY

### 9000 Series

- Quality management for businesses 1987
- Many other ISOs use elements of quality management from 9000s
- In ISO 17020, you forego quality management sections if you already have a management system compliant with ISO 9001

### ISO 17025

- For competence of testing and calibration laboratories-1999 For analytical testing laboratories
- Many toxicology laboratories
- Technical requirements for correctness and reliability of tests in a laboratory. Focus on uncertainty, and analytical validation
- 17025 and 17020 have “equal weight” in the world
- Management requirements similar in 17020 and 17025

## MORE OF THOSE 21,740 ISOS

### ISO 15189

- Came after I7025 (2003), based on I7025 and ISO 9001
- Designed for Medical Laboratories
- Emphasizes analytical tests
- Added patient samples, acceptable turnaround, testing in medical emergencies

### ISO 17020!!!!!!

- No use of instrumentation for analytical testing
- RELIANCE ON PROFESSIONAL JUDGEMENT
- Focus on impartiality, independence, confidentiality
- Similar management system as I7025 (9001)

## PESKY AND QUIRKY ISO TERMS

- Inspection: examine closely, to compare against established standards. Involves examination, measurements, testing.
- Inspection: the autopsy
- Inspector: investigator who uses professional judgement at a death scene, forensic pathologist who performs autopsy
- Inspection body: Medical Examiner or Coroner's Office
- Inspection system: rules, procedures, and management for carrying out office functions

ISO 17020

NAME Core  
Accreditation



# ISO 17020 VERSUS NAME CORE ACCREDITATION

## ISO 17020

- Broader, more generic—need to fit for “bodies performing inspections”
- Quality management, Quality management, Quality Management
- Ongoing internal audits for improvement, complaint management
- Technical competence and training emphasis
- Much more expensive
- More management, no medicine

## Core Accreditation

- More specific requirements: 90% of reports in 60 days, Ground faults
- 5 items in checklist on QA (A8)  
4 items on performance evaluation (G8)
- Yearly checklist completion to maintain accreditation
- All facets of operation addressed: photography, histology, facility etc.
- Less expensive
- The practice of medicine

## WHY CAN'T NAME ADMINISTER NAME ACCREDITATION AND ISO ACCREDITATION?

- NAME Core Accreditation belongs to us, we make the rules
- ISO Accreditation is International—we don't make the rules
- ISO Accreditation Services: There's an ISO for that
- Accreditation bodies are accredited to ISO 17011
- Accreditation bodies are signatories to ILAC—International Laboratory Accreditation Cooperation



## EXAMPLES OF ACCREDITATION BODIES

- ANAB
- CAP
- Canada: Standards Council of Canada

Private companies that are accredited to perform ISO Accreditations have a limited number of ISOs in their repertoire.

## ORDER OF OPERATIONS

- ISO 17020 does not supplant NAME Accreditation
- NAME Accreditation is the foundation
- It would be difficult to achieve 17020 without Core Accreditation first
- ISO 17020 is internationally recognized and for NAME Accredited offices that want robust quality management and continual improvement

**TOP PRIORITY**



[4.1-4.2 Bias and Confidentiality](#)

[5.1 Administrative Requirements](#)

[5.2 Organization and Management](#)

[6.1 Personnel](#)

[Quality Assurance and Performance Improvement](#)

[6.21-6.25 Facilities](#)

[6.2.6-6.2.12 Measurement Traceability](#)

[6.2.13-6.2.15 Computers and Defective Equipment](#)

[6.3 Subcontracting](#)

[7.1-7.1.9 Inspection Methods](#)

[7.2-7.4 Handling Inspection Items, Inspection Records, Inspection Reports and Certificates](#)

[7.5-7.6 Complaints and Appeals](#)

[Complaints and Appeals Policy](#)

[Complaint Tracking Form](#)

[8.2-8.3 Management Documentation](#)

[8.4 Management System Documentation, Control of Records](#)

**ISO 8.5- 8.8**

[AF Chapter 22 Internal Audit](#)

[8.6-8.7 Campobosso](#)

[ISO 8.5- 8.8](#)

A complete set of sample ISO 17020 policies is available on the NAME website, under the Inspection/ Accreditation Tab



NAME ISO 17020 TRANSITION  
SUBCOMMITTEE

Commercial: Part 2

**TIME THE DEVOURER OF ALL  
THINGS.**

Metamorphoses, IX, l. 500

# Practical Aspects of ISO Accreditation

Amy C. Gruszecki, MSFS, DO

The logo for American Forensics is displayed within a white rectangular box. The word "American" is written in a dark blue, sans-serif font. The word "Forensics" is written in a bold, red, sans-serif font. A magnifying glass icon is positioned over the letter 'n' in "Forensics", with its handle extending downwards and to the right.

**American**  
**Forensics**

# ISO Accreditation

- ISO is based on documentation and chain of custody procedures
- It is applicable to many organizations -manufacturing, health care, and forensics organizations.
- In my experience very similar to a CAP inspection.

# ISO Accreditation

- ISO Accreditation goes hand in hand with NAME core accreditation.
- What NAME requires for accreditation - ISO requires proof that it is being done.
- Example policies are present on the NAME website.

# ISO Accreditation

- Simplified - ISO is
  - saying in a procedure that you do something
  - and proving up that you do it
  - keeping a chain of custody.

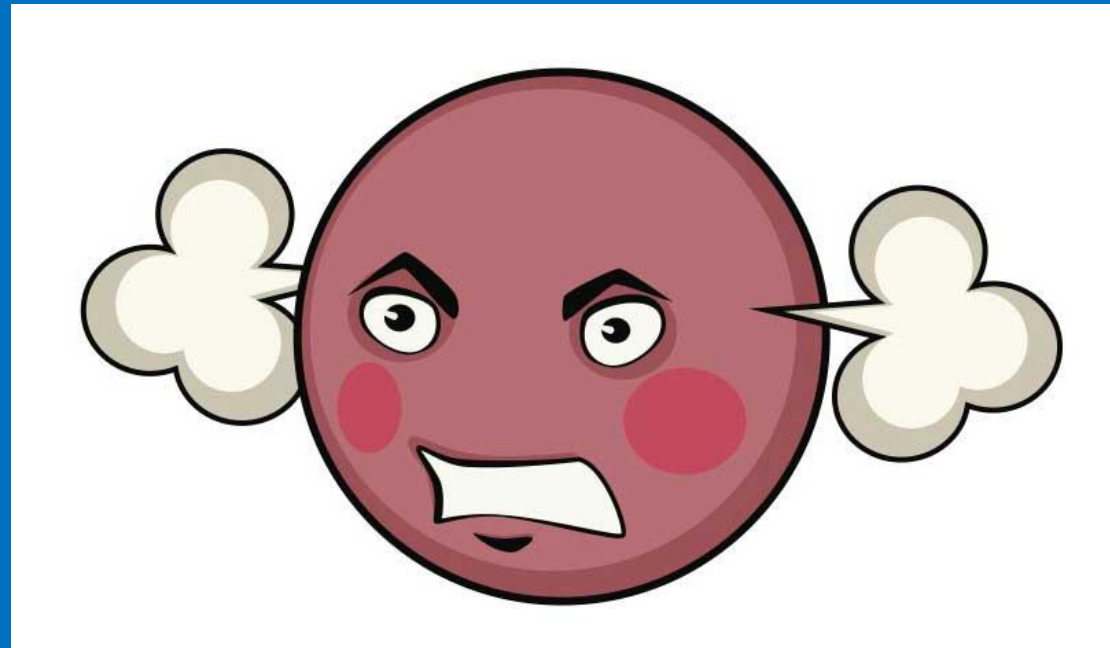
# Must demonstrate

- Confidentiality
- No conflict of interest

# Examples

- track the time an autopsy exam starts
  - What time the body is removed from the cooler and by whom
  - What time the exam ends
  - when stock tissue is put away and by whom
- 
- Easy for large organizations with a LIMS
  - Smaller organizations can use paper documentation

# Some points of contention



# Proficiency testing

- ANAB has accepted the proficiency testing approved by NAME
  - The ASCP case studies (Check Samples)

# Calibration

- Calibrate scales
- Rulers that are calibrated (these can be bought!)
- Calibration must be traceable (means there is a certificate).

# Witnessing

- Need to observe another forensic pathologist performing an autopsy.
- Need to observe court testimony

No defined time intervals!

# Resources involved

- Time
- Lots of office supplies!
- The application fees
  
- Can use a consultant – though not necessary.



# ISO 17020 AND 17025

Cook County Medical Examiner's Office

# BENEFITS OF ISO ACCREDITATION

- Uniformity of quality systems
- Internationally recognized standard of quality
- Process improvement
- Decreases mistakes
- Regulatory compliance
- Specific expectations

# PROCESS TO ACCREDITATION

- In depth review of all current procedures and processes
- Compare current procedures and processes to ISO 17020 standard requirements
- Implementation of ISO 17020 requirements
- Quality Manual is essential
- Quality Manager to oversee process

# PROCESS TO ACCREDITATION

- Document root cause analysis and corrective actions for non conformances
- Document management system to house SOPs, non conformances, and proficiency testing

# ISO 17020 CHALLENGES

- Cost of Accreditation
- Determination of proper scope
- Extensive checklist requirements
- All requirements must be met prior to being granted accreditation. (0 deficiencies allowed)
- Requires a dedicated quality manager to oversee process
- Testing laboratories require ISO 17025 accreditation

## PROCESS CHALLENGES

- NAME and ISO inspection concurrently requires extensive preparation
- ISO stresses on quality management and chain of custody
- NAME stresses on work environment and medicolegal functions of the office.

Government of the District of Columbia  
OFFICE OF THE CHIEF MEDICAL EXAMINER

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# Preparing for Accreditation ISO-017020:2012

**Roger A. Mitchell Jr. MD**

Chief Medical Examiner

District of Columbia  
Office of the Chief Medical Examiner



# Dual Accreditation

**NATIONAL ACCREDITATION**  
(National Association of Medical Examiners)

**TO**

**INTERNATIONAL ACCREDITATION**  
(ISO/IEC 17020:2012 Conformity assessment-Requirements for  
the operation of various types of bodies performing inspection)

**TO**

**DUAL ACCREDITATION**



# Investment in ISO Accreditation Process

- Investment is to ensure strong foundation and sustainability.
  - Reorganization of Records Division to Include Quality Management
  - Purchased/Maintained Quality Software
  - Identified and Trained Quality Manager in ISO process
  - Developed Internal Quality Committee
    - Select Managers meet monthly to discuss quality related issues
  - Development of Executive QCAR Review

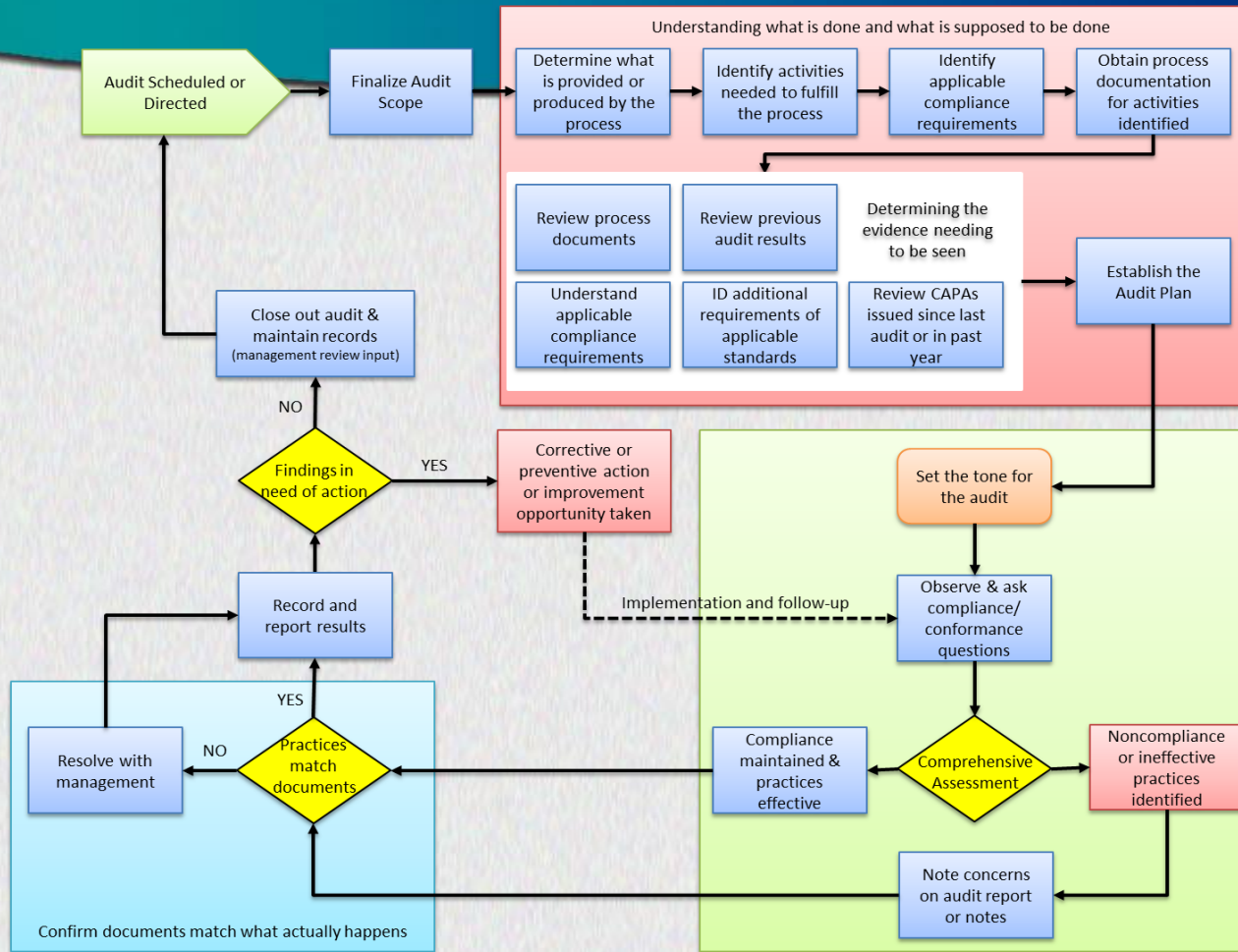


# Additional Investment

- Investment in an ISO Quality Consultant
  - Performed Gap Analysis to for ISO Compliance
  - Performed ISO 017020 – NAME Accreditation Checklist Crosswalk
  - Prepared Agency for Internal Audit
  - Performed Internal Audit
    - Established Standard Operating Procedure for the Internal Audit.



# Internal Audit Flow Diagram



# Non-Conformities Identified

- Health & Safety (3)
- Proficiency Testing (5)
- Personnel/Training (3)
- Expert Testimony (1)
- Calibration (1)
- Evidence Storage (2)
- Chemical Log (2)
- Labeling Reagents (1)

**18 Total  
Non-  
Conformities**



# Continued Preparation

## ISO 17020 ACCREDITATION PREPARATION

1. Written Procedures for Evidence (security/control/handling)
  - ✓ SOP Improvement - SOP # Mort 1.005 – Evidence Collection and Handling
2. Written Reports
  - ✓ Exam Reports (Autopsy and External)
  - ✓ Investigation Reports
  - ✓ Anthropology Reports
3. Technical and Administrative Review of Reports and Supporting Records
  - ✓ SOP Development - SOP # QC 1.001
4. Testimony Monitoring/Moot Court Training for Forensic Pathologists and Death Investigator
  - MOU Development with the Office of the Attorney General (OAG)
5. Technical Procedures
  - ✓ SOP Development - Death Investigations
6. Training program
  - ✓ Training Manual Draft completed
7. Proficiency testing
  - Death investigations, Pathology, and Anthropology
8. Corrective and Preventative Action Process
  - ✓ SOP # QC 1.001
  - ✓ SOP # QC1.003



# Appropriation

- **Supervisory Records Management Specialist – Grade MS14 FY2015 - \$8,333.52**
  - Move from IT Specialist (\$101,860) to Supervisory Records Mgt Specialist (\$110,193.52)
- **Training (\$2000 per person for \$12,000)**
  - ISO Materials \$2600
- **Qualtrax Implementation and Training - \$71,415**
  - Qualtrax Maintenance \$12,500
- **Quality Assurance Specialist – Grade CS11, Step 7 FY2016 - \$5765**
  - Move from Records Management Specialist (\$59,049) to Quality Assurance Specialist (\$64,814)
- **ISO Consultant - Precision Digital Forensics \$50,000**
- **Quality Assurance Specialist – Grade CS12, Step 9 – FY2017 – New Position - \$92,250**
- **ANAB ISO Inspection Cost – \$18,600 Initial Year**

**\$189,548.52**  
**Investment over ~3 years**

