COLLEGE of AMERICAN PATHOLOGISTS

The CAP Biorepository Accreditation Program

Seven Years-Strong and Evolving to Support Precision Medicine

Shannon J. McCall, MD, FCAP
Vice-Chair, CAP BAP Committee

May 7, 2019

Disclosures

- **Shannon J. McCall, MD, FCAP has no significant financial interest with the providers of the services that will be discussed or could, in any way, influence the material to be presented.**

- **Shannon J. McCall, MD, FCAP serves, on a volunteer-basis, as Vice-chair of the College of American Pathologists' Biorepository Accreditation Program Committee.**

College of American Pathologists (CAP)

- **Headquartered in Northfield, IL**
- **World's largest association composed exclusively of board-certified pathologists**
  - **All pathologist members are Fellows (FCAP) & are board-certified.**
  - **The CAP is considered the leader in laboratory quality assurance and advocates for high-quality and cost-effective medical care.**

CAP

U.S. Clinical Laboratory Regulations: CLIA

- **"CLIA sets standards designed to improve quality in all laboratory testing and includes specifications for quality control, quality assurance, patient test management, personnel and proficiency testing."**

https://wonder.cdc.gov/wonder/prevguid/p0000215/p0000215.asp
Accessed 8/15/2018

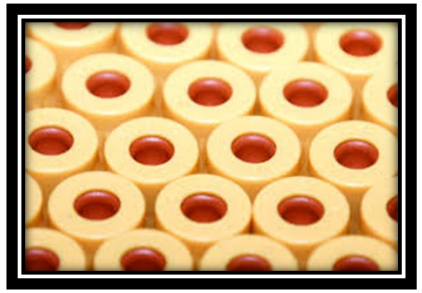
- ***CAP has 'deemed status' from the U.S. Government to inspect laboratories for CLIA.***

CAP

College of American Pathologists (CAP)

- **CAP designed and implemented its clinical Laboratory Accreditation Program (LAP) to exceed U.S. “CLIA” standards.**
- **CAP has >50-year track record of success and leadership in the clinical laboratory accreditation industry.**
- **There are over 8,000 global CAP-accredited laboratories.**
- **CAP’s proven inspector/peer model combines scientific expertise with third-party validation of standards.**

The Need for Biorepository Accreditation Led to CAP Program Development in 2012



"The lack of standardized, high-quality biospecimens has been widely recognized as one of the most significant roadblocks to the progress of cancer research"

-- National Cancer Institute,

Biorepositories & Biospecimen Research Branch

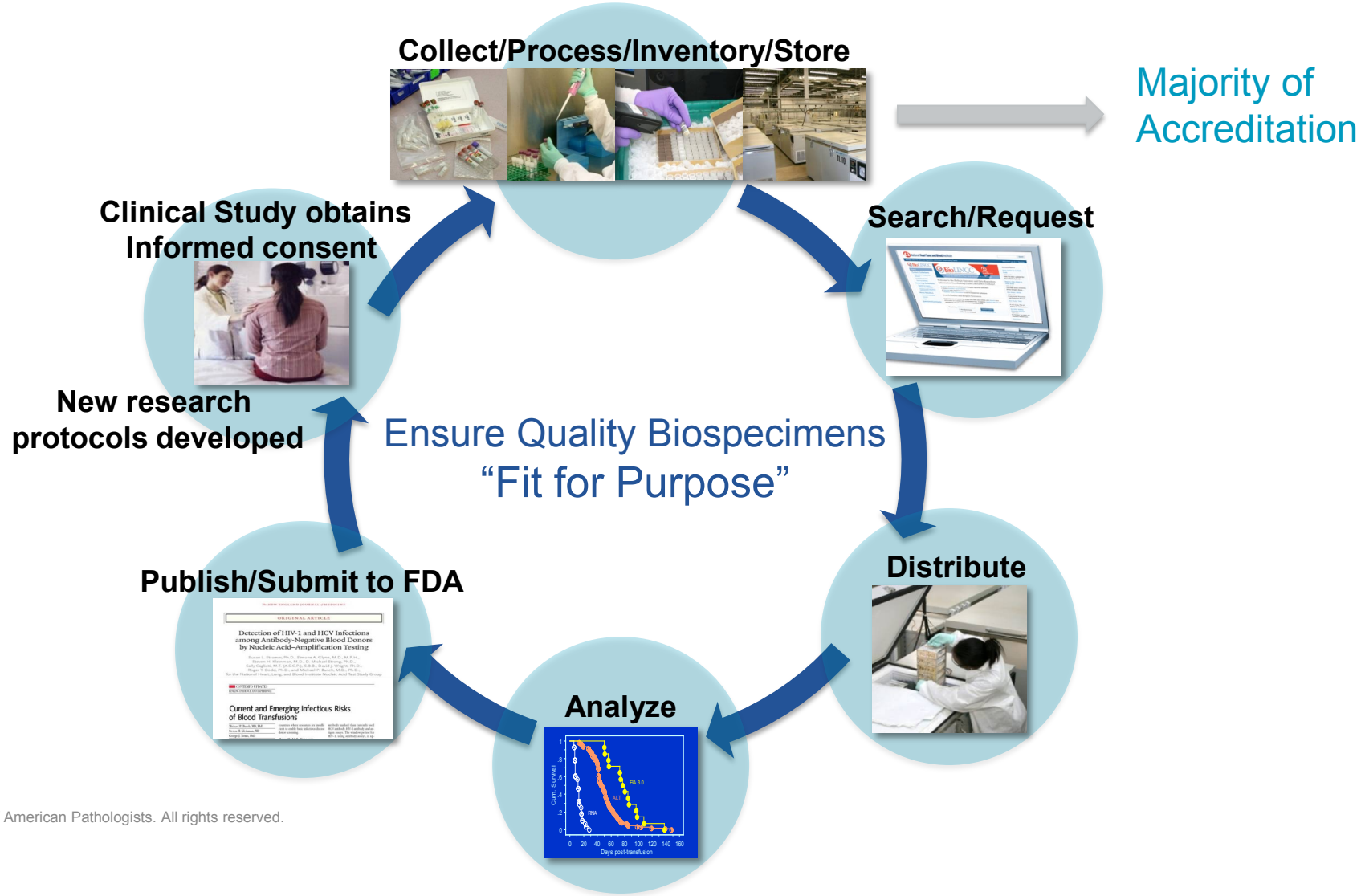
www.biospecimens.cancer.gov

The CAP Biorepository Accreditation Program Incorporates Best Practices from:

- International Society for Biological and Environmental Repositories (ISBER)
- NCI's Office of Biorepositories and Biospecimen Research
- Organization for Economic Cooperation and Development
- Centers for Medicare & Medicaid Services
- College of American Pathologists

CAP

CAP Biorepository Accreditation Covers the Biospecimen Lifecycle



Standards and Checklist requirements

The BAP has four *Standards* and all must be met to be accredited:

I. Director and Personnel
II. Physical Resources
III. Quality Management
IV. Administrative Requirements

CAP

CAP Standards Enforced Through Accreditation Checklists

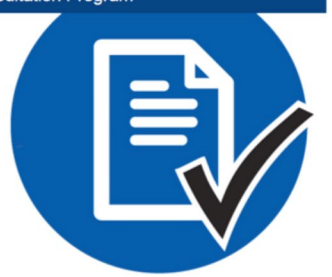
- Customized for biorepositories based on their services
- Provided for inspection preparation

COLLEGE of AMERICAN PATHOLOGISTS

Master

Biorepository Checklist

CAP Accreditation Program



College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
www.cap.org

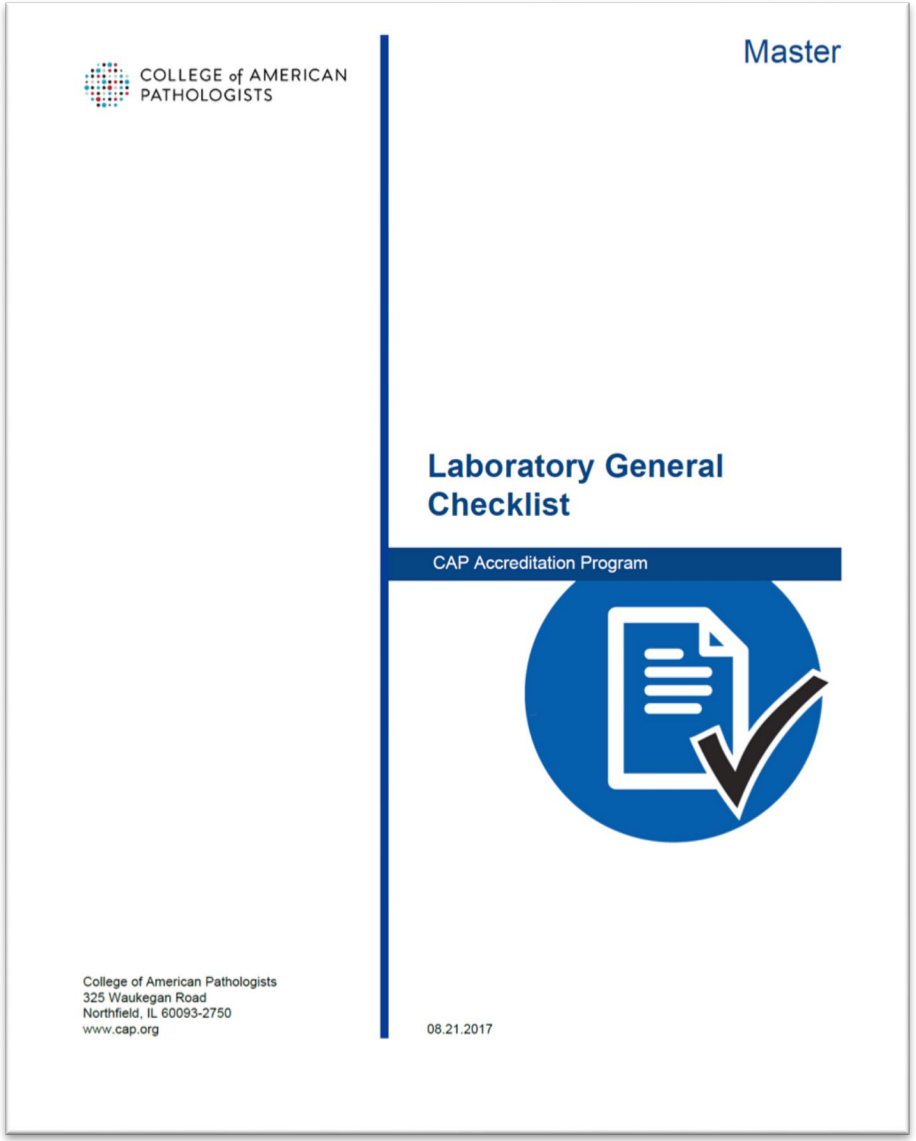
08.21.2017

Biorepository Checklist

TABLE OF CONTENTS

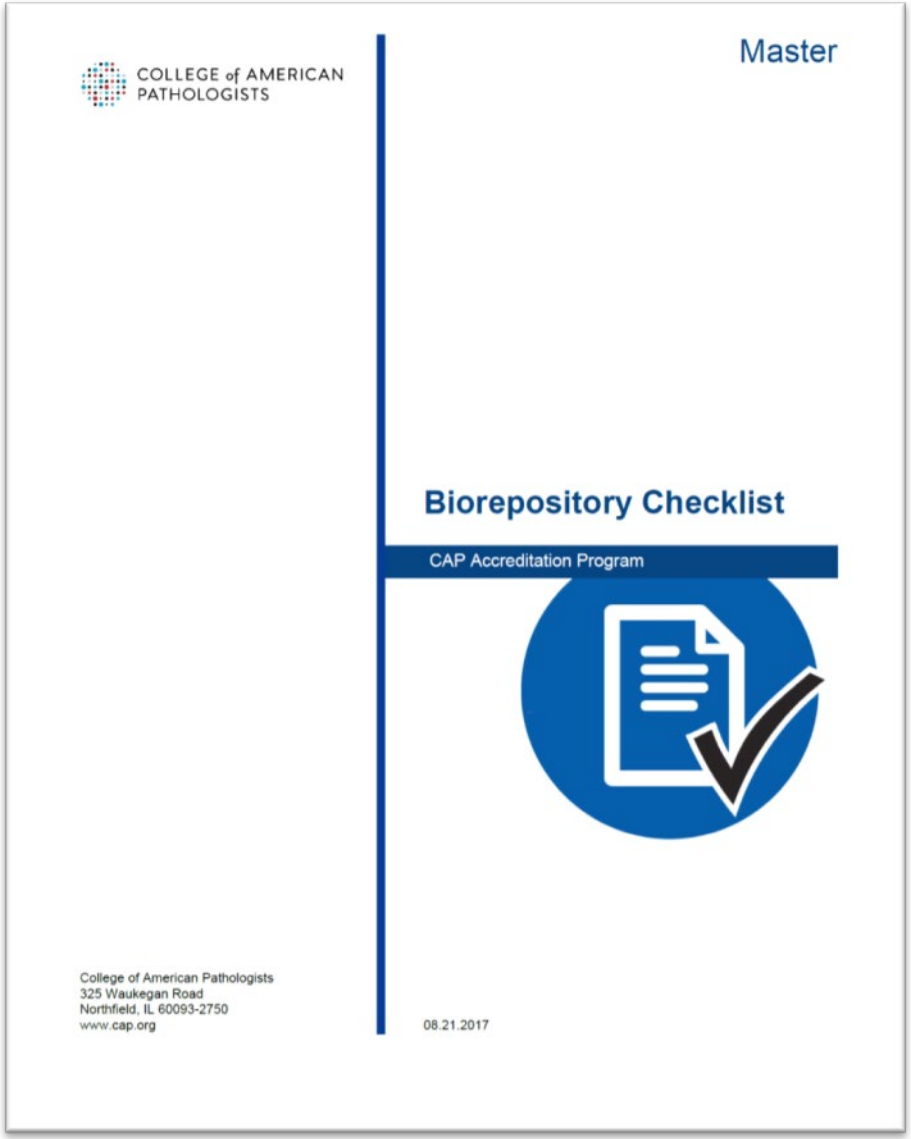
CAP “Lab General” Checklist Requirements – Sections

- Policies and Procedures
- Quality Management
- Personnel
- Director Qualifications
- Director Oversight Responsibilities
- Director Not On-Site Full Time
- Operational Leadership/Management
- Physical Facilities
- General Safety
- Biological Safety
- Fire Safety
- Chemical Safety
- Radiation Safety



CAP "Biorepository" Checklist Requirements – Sections

- Informed consent, Institutional Review Board
- Specimen Collection and Handling
- Biospecimen Quality Assurance
- DNA/RNA Extraction
- Cell fractionation and tissue culture
- Histology
- Digital Imaging (photomicrographs and whole slide imaging)
- Tissue Microarray (TMA)
- Laser Capture Microdissection (LCM)
- Instruments and Equipment
- Storage
- Information Technology Systems
- Inventory Management

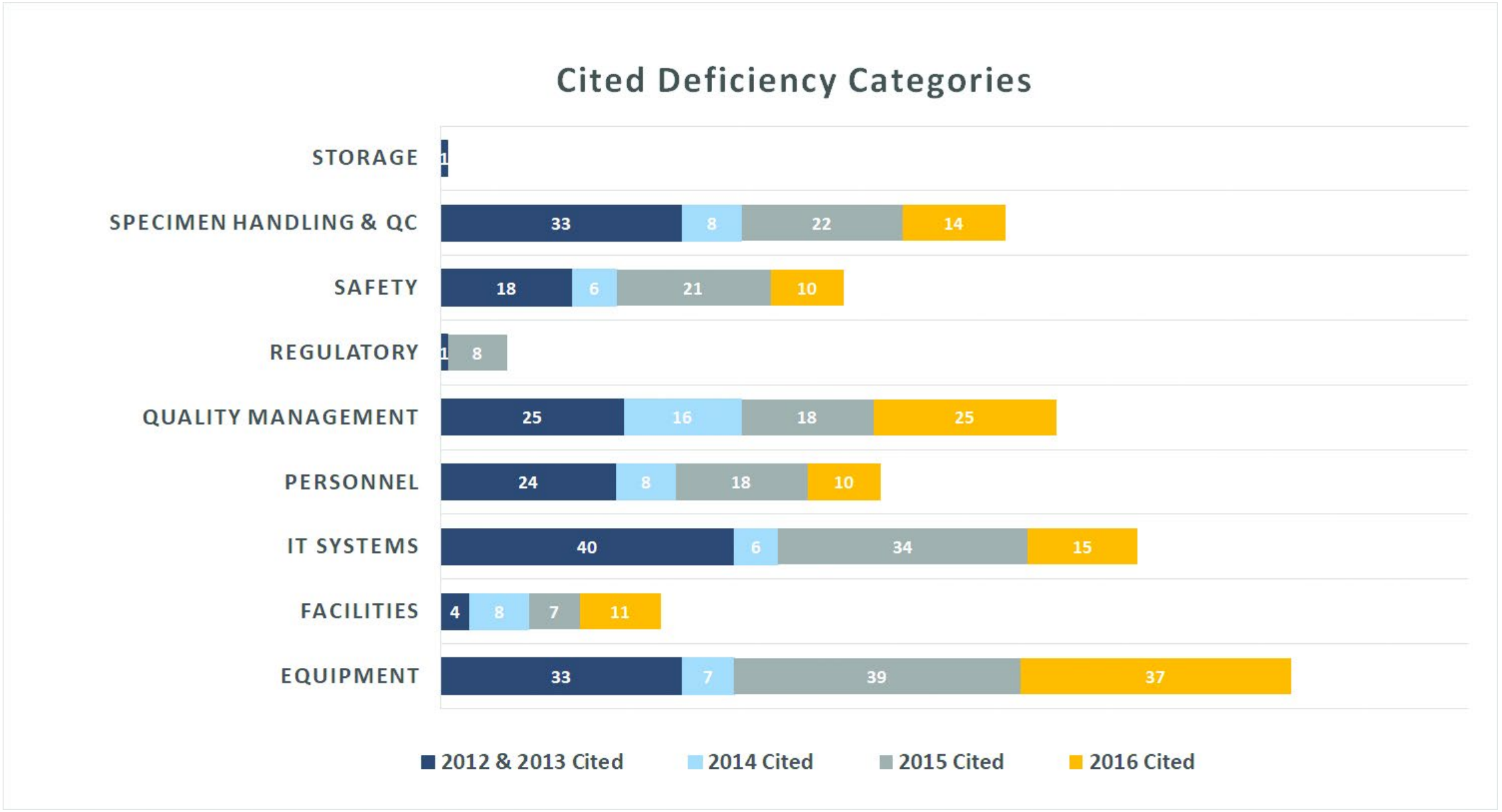


Review of the First Five Years of Inspections

- **90 total inspections**
  - **61 initial inspections**
  - **29 re-inspections**
    - **Second-cycle, or**
    - **Second visit to follow-up on concerns**
- **527 total deficiencies**

CAP

McCall SJ et al.,
Biopreservation & Biobanking, 2018



CAP

McCall SJ et al.,
Biopreservation & Biobanking, 2018

Examples of Recurrent Cited Deficiencies

- **Equipment: Freezer alarm checks incomplete, equipment function checks incomplete**
- **Quality Management: Incomplete personnel records, lack of key performance indicators in the Quality Management Plan**
- **IT Systems: Lack of IT system testing, lack of IT system audit trail criteria**

CAP

McCall SJ et al.,
Biopreservation & Biobanking, 2018

How is the CAP Biorepository Accreditation Program Evolving to Support Precision Medicine?

CAP

U.S. Confusion over CLIA/CAP

- **Recall that CLIA is for clinical laboratories; biobanks are exempt and ineligible for CLIA licensure.**
- **2015 Precision Medicine Initiative (PMI) Request for Applications to become the Cohort Program Biobank requested that the applicant use processes "consistent with CLIA" or "CLIA-compliant"**
- **No accepted definition or surrogate accreditation program for CLIA in biorepositories was suggested in that RFA.**

CAP

“CLIA-compliant”

- **The use of the term “CLIA-compliant” aligns with the idea that CLIA (or more stringent) requirements on biorepositories will ensure biospecimen quality and reproducibility for research and test development.**

- **Recall CAP has ‘deemed status’ from the U.S. Government to inspect for CLIA. Therefore CAP can externally validating the “CLIA-compliance” of a biorepository.**

CAP

“CLIA-compliant”: How Could This Be Implemented/Formalized?

- **The CAP Biorepository Accreditation Program did not create the term “CLIA-compliant”**
- **However, CAP recognized the importance of the term and designed a strategy to formalize this.**

CAP

CAP Biorepository Accreditation Program (BAP)
Alignment with CAP Laboratory Accreditation Program (LAP)

- **Substantial overlap of checklists already existed**
- **2018-2019: alignment of checklists completed**
- **Next steps:**
  - **Shorten inspection cycle as per LAP (Q3 years → Q2 years)**
  - **Align inspection calendar of biorepositories with their related clinical labs if applicable/beneficial**

CAP

CAP Biorepository Accreditation: Future State

- **Biorepository is one of many inspection checklists and accreditation options offered by CAP**
- **Checklists apply according to the lab's (or biorepository's) activity menu**
- **If accredited in this way, a biorepository that performs limited patient sample testing is eligible for CLIA license through the LAP.**

CAP

Sample Benefits to Precision Medicine

- **Research benefit: Biorepositories could perform new assay testing for FDA or clinical trials in a CLIA environment. (If the activity is not covered on the Biorepository Checklist, the relevant LAP checklist would apply – e.g., Molecular Pathology)**

- **Patient benefit: Accommodates sample sharing between the clinical laboratory and the biorepository (e.g., need to retrieve research tissue for additional clinical testing)**

- **Research and patient benefit: Preanalytic variable control ensures biorepository samples are fit for purpose, even if the purpose is eventual clinical testing (e.g., HER2 testing)**

CAP

COLLEGE of AMERICAN PATHOLOGISTS