

CEO Update to CCRHB

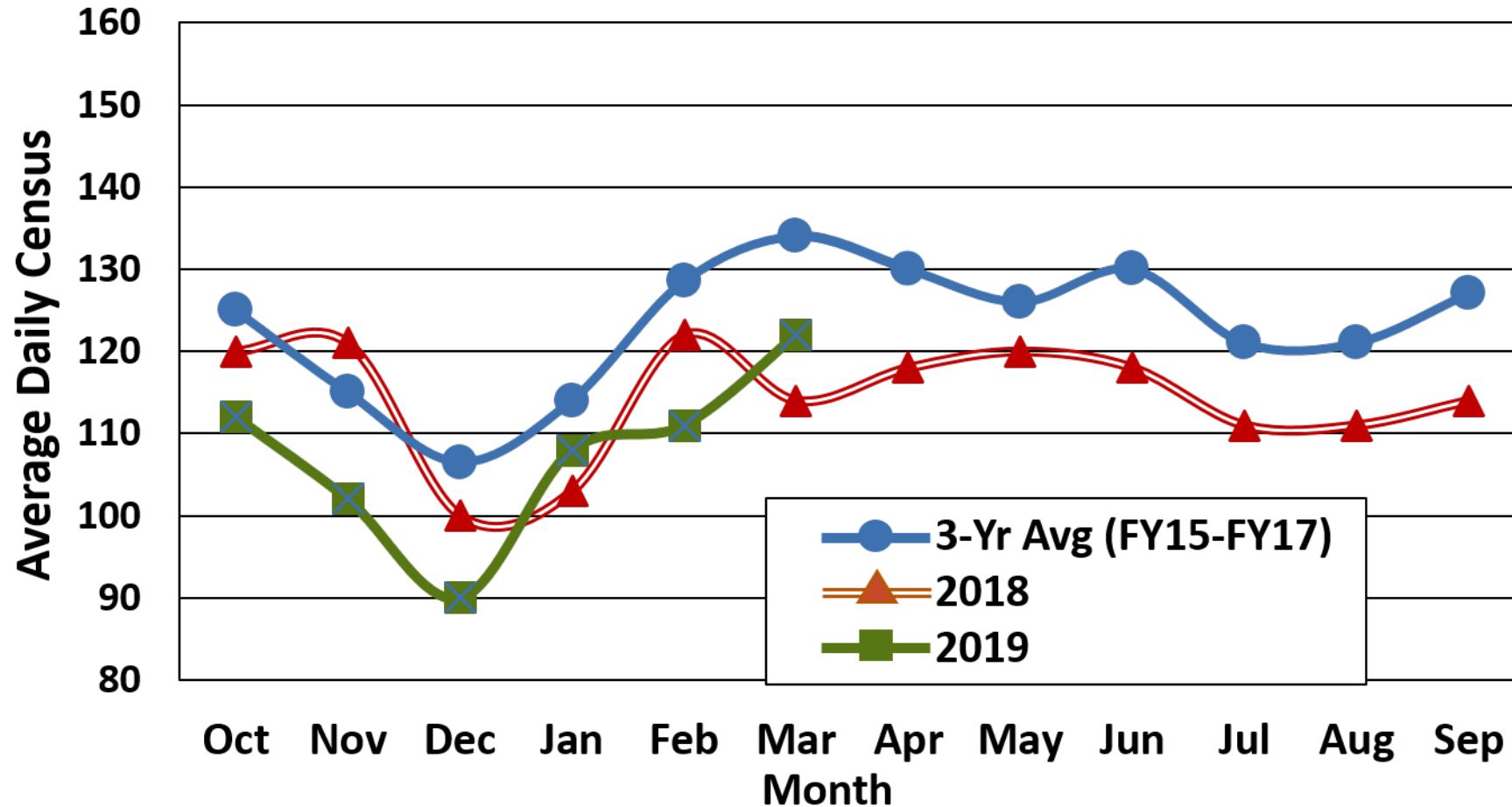
12 April 2019

James K. Gilman, MD

MG, USA (ret)

Average Daily Census

as of March 31, 2019



ADC Stats

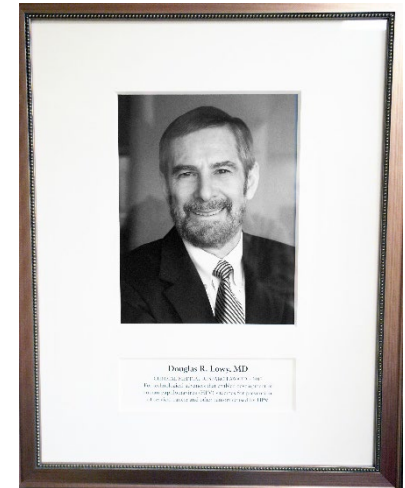
- 3-Year Average (FY 2015-2017) = 126.6
- Year End FY 2018: 113.9
- Year-to-Date FY 2019 (as of 3/31/2019): 107.6

Leadership Changes

Departures:

1) **Norman E. “Ned” Sharpless, MD, Director, National Cancer Institute (NCI);
Chair, Clinical Center Governing Board (CCGB) to FDA**

- **New Chair, CCGB: Douglas R. Lowy, M.D., Acting Director, NCI
Chief, Laboratory of Cellular Oncology, CCR, NCI**



2) **Colleen McGowan, CC Executive Officer to Chief, NIH Office of Research Services**

- **Acting CC Executive Officer: Eric Cole, MS, FACHE**



1st Graduates of CC Leadership Training Course



CC Fundamentals in Leadership Training Course

1st Graduates on March 21st

- **Course designed to:**
 - support ongoing leadership development
 - deepen individual capacity
 - strengthen a collective leadership culture in the CC
- **January – March 2019, 6 sessions**
- **16 participants**
- **Varied learning methods included:**
 - assessments to deepen self-awareness
 - interactions with CC Executive Leaders and NIH partners
- **CC OWMD call for nominations for upcoming cohorts coming soon!**

External Reviews - IT

- **Department of Homeland Security (DHS) HVA (High Value Asset) Review**
 - Focus: CRIS only
 - Interviews and documentation requests submitted
 - DHS to provide draft review and present April 15
 - Final from DHS due in May
- **Office of the Inspector General (OIG) audit**
 - Focus: CRIS only
 - Initial Technical Interviews completed
 - Initial documentation requests submitted to NIH OCIO
 - Documentation requests from Technical Interview process will be provided to CC in two weeks
- **Government Accounting Office (GAO) audit**
 - Focus: all of NIH
 - CC IT and CRIS kickoff completed
 - Documentation requests are being initiated from GAO

External Reviews - Pharmacy

Recent

- **Recent**: February/March 2019
- 483 released and posted on 3/22/19:
https://www.cc.nih.gov/phar/pharm_services.html
- **7** observations

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 2/19/2019-3/6/2019* FEI NUMBER 3011547221
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: James K. Gilman, Clinical Center CEO	
FIRM NAME NIH Clinical Center Pharmacy Department	STREET ADDRESS 10 Center Drive, Building #10
CITY, STATE AND ZIP CODE Bethesda, MD 20892-0001	TYPE OF ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products
<small>THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.</small>	

Previous

- **Previous**: May/June 2015
- 6/4/15:PDS Sterile activities suspended
- **17** observations

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Baltimore District Office # 410-779-5454 6000 Metro Drive; Suite 101 Baltimore, MD 21215 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 5/19, 20, 21, 26, and 29/2015 FEI NUMBER 3011547221
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Mr. Robert (NMI) DeChristoforo, Chief Pharmacy Department	
FIRM NAME NIH - Clinical Center Pharmacy	STREET ADDRESS 10 Center Drive; Building 10; Room 4436
CITY, STATE AND ZIP CODE Bethesda, MD 20892	TYPE OF ESTABLISHMENT INSPECTED Hospital Pharmacy
<small>THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.</small>	

External Reviews – Pharmacy *(continued)*

- **Observations from 483 released on March 22, 2019:**

1. Aseptic manipulations are performed in an area where the unidirectional movement of air in the ISO 5 area is disrupted.
2. Deficiencies were noted with aseptic processing performed within the ISO 5 areas.
3. Cleaning pads used in the ISO 5 classified aseptic processing areas were not sterile.
4. Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.
5. Your facility design allowed the influx of poor quality air into a higher classified area.
6. The material of construction of the clean room walls is not suitable for the intended use.
7. Your facility was designed and/or operated in a way that permits poor flow of personnel.

22 March 2019

- **CCRHB members notified**
- **483 posted to CC website**
- **All pharmacy staff informed**
- **Email message to all CC staff emphasizing how far we have come since 2015**

Clinical Center Planning Meeting

March 18, 2019



>50 Institute & CC Leaders

- Reviewed:
 - Annual CC Priorities
 - Status of Capital Investment Fund (CIF)
 - Protocol and Census Data
 - CCE Activity-to-date
- Assumptions that Need to be Challenged:
 - There will always be a CC
 - There will always be an in-patient facility
 - Other places cannot do what we do
 - Build it & they will come
- 3 Main Things:
 1. Patient safety & clinical quality
 2. Get the new SRLM building started
 3. Increase CC utilization – cannot be done without IC help

It isn't all about the
in-patient census

But it is about the
in-patient census

CC Strategic Plan Preview

**Final Review in April with Strategic Planning Reboot Group
(>30 CC leaders)**

Review/Approval by CCGB

Presentation to CCRHB

GOAL: Completion 2019

The NIH Clinical Center at 65:
People
Places
&
Capabilities

Anti – Harassment Update

The screenshot shows the NIH Anti-Sexual Harassment website. The top navigation bar includes links for Health Information, Grants & Funding, News & Events, Research & Training, Institutes at NIH, and About NIH. Below this, a sub-navigation bar reads 'Home » Research & Training » Anti Sexual Harassment'. The main heading is 'ANTI-SEXUAL HARASSMENT'. On the left, a sidebar lists 'Anti-Sexual Harassment' with sub-links for 'For NIH Staff', 'For NIH Awardee Organizations', 'Laws and Regulations', and 'Frequently Asked Questions'. The main content area is titled 'For NIH Staff' and features a paragraph stating NIH's commitment to a safe work environment. To the right, an 'Important Contacts' section lists key roles like the NIH Civil Program and the Office of the Ombudsman. A bottom note indicates the page was last reviewed on December 20, 2018.

The screenshot displays the NIH Workplace Climate and Harassment Survey announcement page. The top navigation bar includes links for About Us, Science of Diversity, Building Evidence, Sociocultural Factors, Sustaining Diversity, Programs & Partnerships, and Home. The main heading is 'NIH Workplace Climate and Harassment Survey'. A prominent blue banner announces the survey dates as 'January 28th - March 25th' and the 'CC Response Rate = 43.3%'. Below this, a sidebar lists 'NIH Workplace Climate and Harassment Survey' with sub-links for 'About', 'How to Take the Survey', 'FAQ', 'Find Your IC Survey Champion', and 'Find a Place to Take the Survey'. The main content area provides a detailed description of the survey's purpose and how to participate.

Survey Focus: workplace climate experiences that took place within past 12 months covering a range of objective behaviors

The image shows the cover of the 'HARASSMENT IN THE CLINICAL ENVIRONMENT' Briefing Book. The background is a photograph of a healthcare professional in blue scrubs attending to a patient in a hospital bed. The title 'HARASSMENT IN THE CLINICAL ENVIRONMENT' is prominently displayed in white text. Below the title, a quote reads: 'Without our patients we can't make progress. Without our safety we can't have success'. The text 'Briefing Book February 2019' is located in the bottom left corner. At the bottom of the cover, a teal banner lists the contents: 'Key Messages and Summary Events • Timeline • Formation of Response Team • Next Steps'.

Multidisciplinary CC/NIH effort: focused on inappropriate behavior and harassment by patients or visitors toward staff



28 February 2019

**Empire State Building lit up in RDD colors
in honor of Rare Disease patients everywhere**

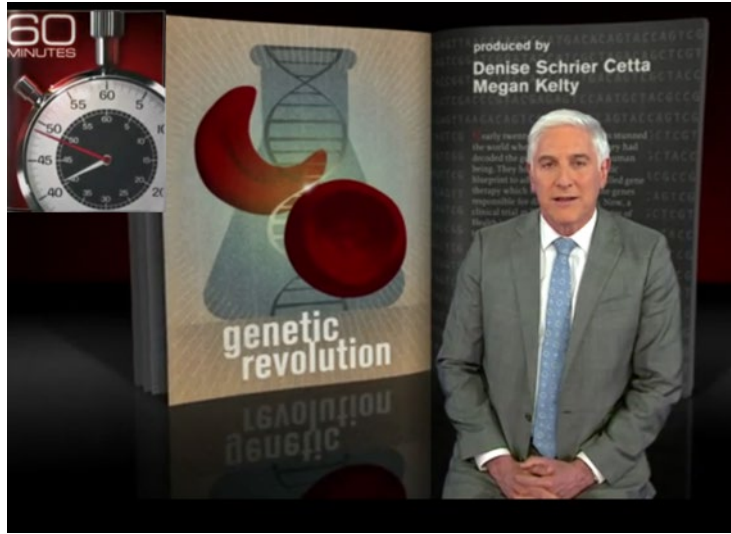
- **>1,100 registrants for NIH RDD**
- **CC Participation:**
 - CC tours
 - Office of Patient Recruitment (OPR) exhibit
 - Panelist, Mandy Mansaray, RN, M.A., Program Coordinator, OPR for Session titled *“No Disease Left Behind, No Patient Left Behind”*

*“What an incredible way to closeout Rare Disease Day 2019 in the United States!
...in honor of the biggest day of the year for 350 million people
around the globe impacted by rare diseases.”*

(Tweet from NORD)

10 March 2019: Feature Media Story

“For the past 15 months we've been following the scientists, and patients, who are ushering in a genetic revolution.”



“I believe this looks like a cure...”
Dr. Collins



“...A clinical trial at the National Institutes of Health is attempting to cure sickle cell anemia, a devastating genetic disease that kills hundreds of thousands of people around the world every year”



Reuter's interview
on 3/11/19



“Thank you to all who make our vital mission possible: dedicated staff and trainees, the public, and most importantly our patients. Patients are the heart of everything we do.

As seen in the 2017 Discovery documentary: First in Human, the medicine of tomorrow starts today. It starts at the NIH Clinical Center. It starts with you.”

Today's Agenda – 12th Meeting on April 12th

9:00 AM	Welcome & Board Chair's Overview ➤ Laura Forese, MD, <i>NewYork-Presbyterian, and Hospital Board Chair</i>
9:05 AM	NIH Director's Remarks ➤ Francis Collins, MD, PhD, <i>Director, NIH</i>
9:20 AM	NIH CC CEO Update ➤ James Gilman, MD, <i>Chief Executive Officer, NIH Clinical Center</i>
9:50 AM	Steam Pipe Incident ➤ James Gilman, MD, <i>Chief Executive Officer, NIH Clinical Center</i>
10:10 AM	Patient Safety & Clinical Quality Update & Clinical Performance Metrics Report ➤ Laura Lee, MS, RN, <i>Director, Clinical Center Office of Patient Safety & Clinical Quality</i>
10:50 AM	Discussion/Break
11:10 AM	Biomedical Translational Research Informatics (BTRIS) ➤ Jose Galvez, MD, <i>Chief, Office of Biomedical Translational Research Informatics</i>
12:00 PM	Lunch
1:00 PM	Clinical Center Electronic Health Record (EHR) Business Case ➤ Maria D. Joyce, MBA, CPA, <i>Chief Financial Officer, NIH Clinical Center</i> ➤ Jon McKeeby, D.Sc., MBA, <i>Chief Information Officer, NIH Clinical Center</i>
2:00 PM	Surgical Services Update ➤ Jeremy Davis, MD, <i>CC Surgeon-in-Chief, Staff Clinician, NCI, Surgical Oncology Program</i> ➤ Andrew Mannes, MD, ME, MBA, <i>Chief, CC Department of Perioperative Medicine (DPM)</i> ➤ Nilka Schulman, MSN, <i>PACU Nurse Manager, CC Nursing Department, Nursing Operations</i> ➤ Myra J. Henley, BSN, RN, CNOR, <i>Operating Room Nurse Manager, CC Nursing Department, Nursing Operations</i>
3:00 PM	Adjournment

**HAPPY
BIRTHDAY**

Laura Lee!

Steam Pipe Incident

12 April 2019

James K. Gilman, MD

MG, USA (ret)

March 11th: Critical Steam Failure in ACRF

STPD of 2019 **“Steam Pipe Disaster”**

No hot water, steam or heating in the ACRF

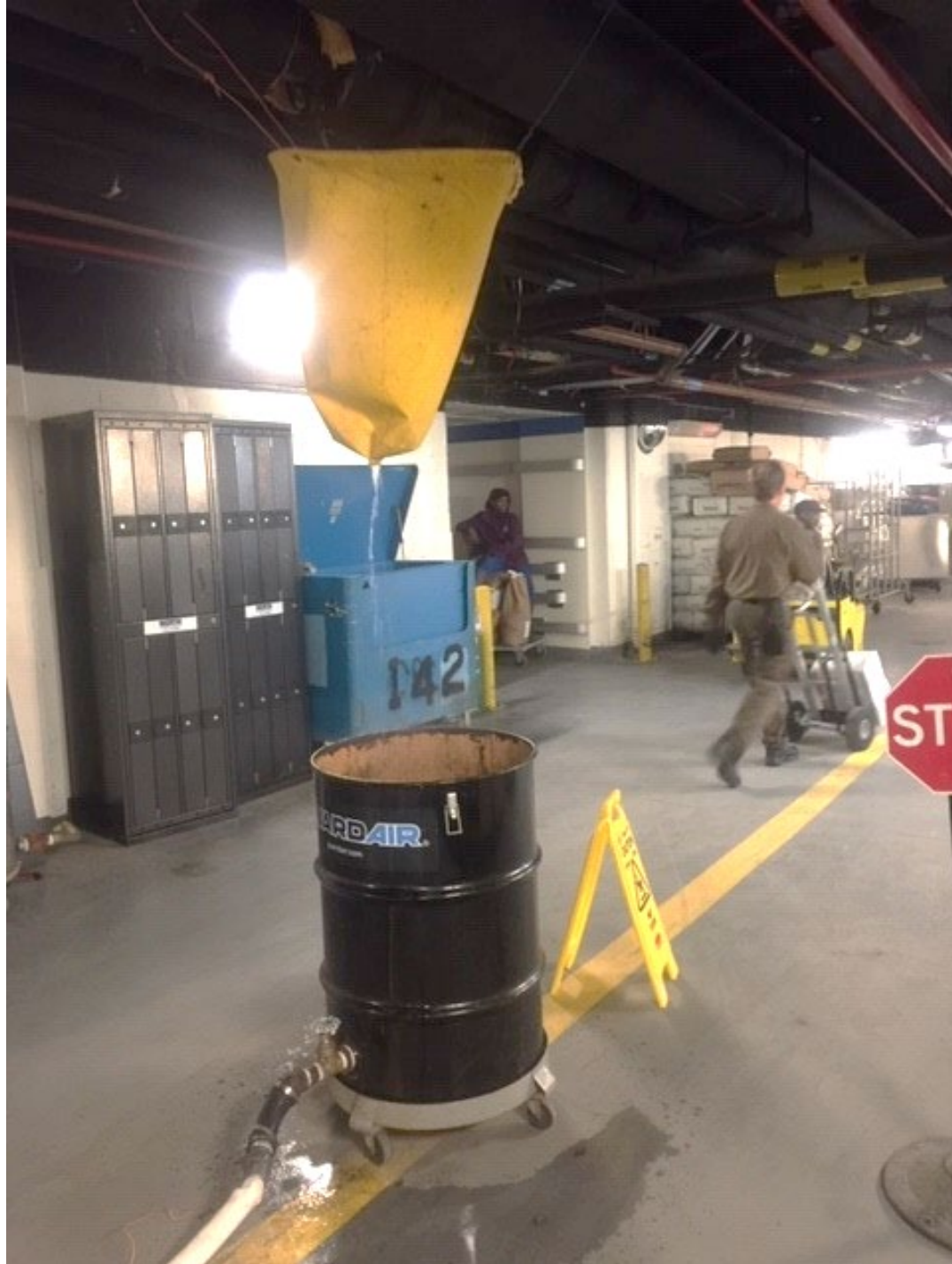
- Steam leak developed in the early morning hours
- Could not be contained for several hours
- Difficulty isolating the steam leak required shutting off all steam to the ACRF and a portion of Magnuson building
- Leak occurred in utility tunnel adjacent to med supply warehouse
- No steam or hot water
- Temperatures during the day were relatively mild
- No OR x 2 days. Clinics displaced for one day (day #2). Interventional radiology also impacted. Sterile processing relocated.
- After day #2, clinical operations returned to normal

Steam Pipe Disaster (2)

- **After day #2, the issue became one of medical supplies**
- **Medical warehouse contents almost all lost**
- **Support of scheduled patient care required detailed management of each day's supply requirements**
- **This phase of the operation is still ongoing**













March 11th Steam Pipe Failure Lessons Learned

- 1. New Surgery, Radiology, & Laboratory Medicine (SRLM) Wing would not have had to cancel surgery**
- 2. New SRLM would not have prevented loss of warehouse contents**
- 3. Office of Research Facilities – steam system redesign so that isolation of leak faster and easier**
- 4. Clinical Center – reevaluate how many supplies on site at any one time. Stage supplies in NIH controlled warehouse in Gaithersburg**



With Gratitude to Bernard Harper & Entire MMD Team!