CDC'S RADIATION BIOASSAY LABORATORY PARTICIPATION IN THE INTEGRATED CONSORTIUM OF LABORATORY NETWORK'S FULL SCALE RADIOLOGICAL LABORATORY EXERCISE

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National Center for Environmental Health
Division of Laboratory Sciences

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Integrated Consortium of Laboratory Networks (ICLN)

EPA **HHS** **DHS** **DOE** **DOD**

DOS **DOI** **DOJ** **DOA**

ICLN Full Scale Radiological Laboratory Exercise

EPA **HHS** **DHS** **DOE**

(CDC & FDA)

Integrated Consortium of Laboratory Networks (ICLN) activities

"Overarching goal is to establish enduring governance policies that **facilitate a coordinated and operational system of laboratory response networks**"

- "Establish methods for **risk-based prioritization** to identify and address key gaps in coverage"
- "**Improve capability for "surge" requirements** and efficiencies in laboratory method development and validation."
- Develop "standards in quality assurance, **proficiency testing, training, and information management and flow among networks**"

CDC'S ICLN Exercise 2014 GOALS

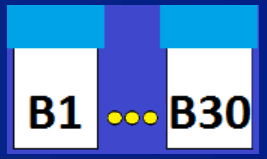
Test the CDC's ability, for 200 spot urine samples, to:

- receive, login, and process
- analyze (screen, identify and quantify)
- perform analytical quality control
- report analytical results
- use the new Division database to:
    - order tests
    - manage sample test and result information
    - produce QC charts/validating analytical run QC
    - produce standard CLIA compliant reports
    - generate ICLN MDE format output files
- upload MDE data files to the ICLN Data Exchange Portal

CDC's Test Sample Production – pooled urine

Collect about 7 liters of urine anonymously and homogenize a portion to generate a 3.6 liter urine pool:

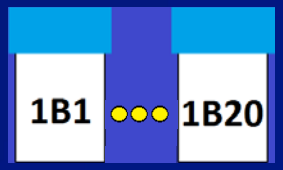
- Spike four 400 mL aliquots, individually:
  - Pu-239 low (9.2×10^{-3} Bq/L) and high (4.6×10^{-2} Bq/L) levels
  - Sr-90 low (200Bq/L) and high (1000 Bq/L) levels.
- Individually aliquot about 25 mL of each nuclide/activity solution into 15 urine cups (producing a total of 60 spiked samples).
- Pour 30 aliquots of the remaining portion of the pool into 30 urine cups.



CDC's Test Sample Production – individual urine samples

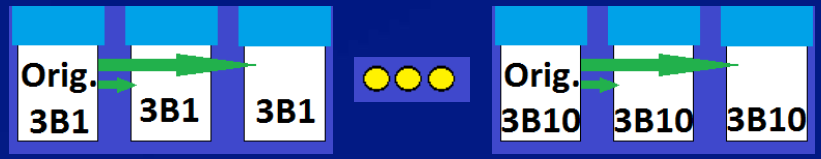
Use the remaining individual urine samples to acquire additional statistical test data on the creatinine analysis system:

Label 20 cups containing the lowest volume of urine as singles.



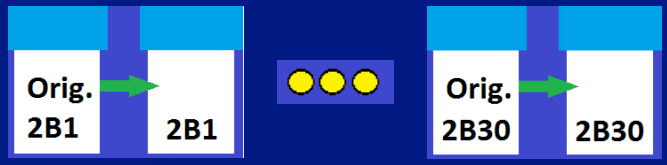
(Single blanks 1 through 20)

Select 10 cups with the highest volume of urine, split each, with random volume aliquots, none being less than 20 mL, into the original cup and two new cups, and label as triplicates.



(Triplicate blanks 1 through 10)

Split the remaining 30 cups in two by pouring approximately 25 mL into a clean cup, and labeling both cups as duplicates.



(Duplicate blanks 1 through 30)

60 blank pool samples give data on creatinine system precision, and singles, duplicates and triplicates provide data on variability & precision.

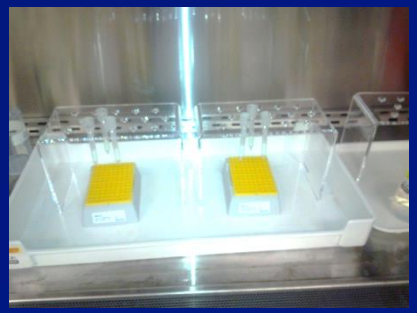
Sample Receipt, Login, and Aliquoting

- Presented frozen samples to the Emergency Response (ER) Sample Logistics Group.
- Thawed spiked samples in a warm water bath using a Radiation Team laboratory sink, thawed blanks in ER Sample Logistics' flowing water baths.
- Meanwhile, associated randomized sample IDs with content based IDs in the LIMS to mask the samples' content.
- In the Radiation Lab, aliquoted all samples for Sr-90 and Pu-239 into containers labeled with corresponding Analysis IDs.
- Placed samples in order of Analysis ID and presented them to the analysts.

Flowing water baths, auto-aliquoters

Analyses – Gross α/β, Sr-90, Pu-239

Eichrom Sr vacuum SPE



Eichrom TEVA gravity SPE

Perkin Elmer Quantulus LSC

Thermo Element XR SF-ICP-MS

Results - Gross α/β

Spike values: Pu-239 low = 9.2x10-3 Bq/L and high = 4.6x10-2 Bq/L
Sr-90 low = 200Bq/L) and high = 1000 Bq/L

Gross α (CPS/L)	Mean	SD	
Low Pu-239 α	-0.14	1.28	n=15
High Pu-239 α	0.16	1.24	n=15
Low Sr-90 crosstalk β to α	10	14	n=15
High Sr-90 crosstalk β to α	41	51	n=15
Blank pool α	0.19	1.13	n=30
No Sr-90/Pu-239 α	0.50	1.47	n=140
Gross β (CPS/L)			
Low Sr-90 β	443	34	n=15
High Sr-90 β	2097	53	n=15
Blank pool β	37.7	7.2	n=30
No Sr-90/Pu-239 β	36.3	19.2	n=140

Results – Pu-239, Sr-90 & Creatinine

Spike values: Pu-239 low = 9.2x10-3 Bq/L and high = 4.6x10-2 Bq/L
Sr-90 low = 200Bq/L) and high = 1000 Bq/L

Pu-239, Bq/L	Mean	SD	
Low Spike	9.04E-03	4.16E-04	n=15
High Spike	4.51E-02	1.07E-03	n=15
No Pu Spike	4.46E-06	3.71E-04	n=170
Blank pool	4.84E-05	3.62E-04	n=30

Sr-90, Bq/L	Mean	SD	
Low Spike	199.5	15.4	n=15
High Spike	979.9	39.9	n=15

Creatinine, mg/dL	Mean	SD	Range	
Urine pool	58.98	0.89	57 to 62	n=90
Urine singles*	53.22	30.12	10 to 130	n=60

* All results for splits of individual urines were within 2 mg/dL of one another.

Issues/Lessons Identified

- Spikes thawed in Rad Team Sink water bath – cups bulged and tipped.
- Pu-239 analyte was not checked in the database analysis panel screen.
- Aliquot ID for "DLS Creatinine" was assigned during sample setup/login, but the ID for "Rad Creatinine" should have been assigned.
- "Sample login mismatch error" occurred due to use of a sample login spreadsheet that our database required be completely filled in to work. Switched to use of the "generic long form".
- Autosampler for the Pu-239 analysis stalled.
- Pu-239 autosampler got worse and worse. Replaced it after the 5th batch.

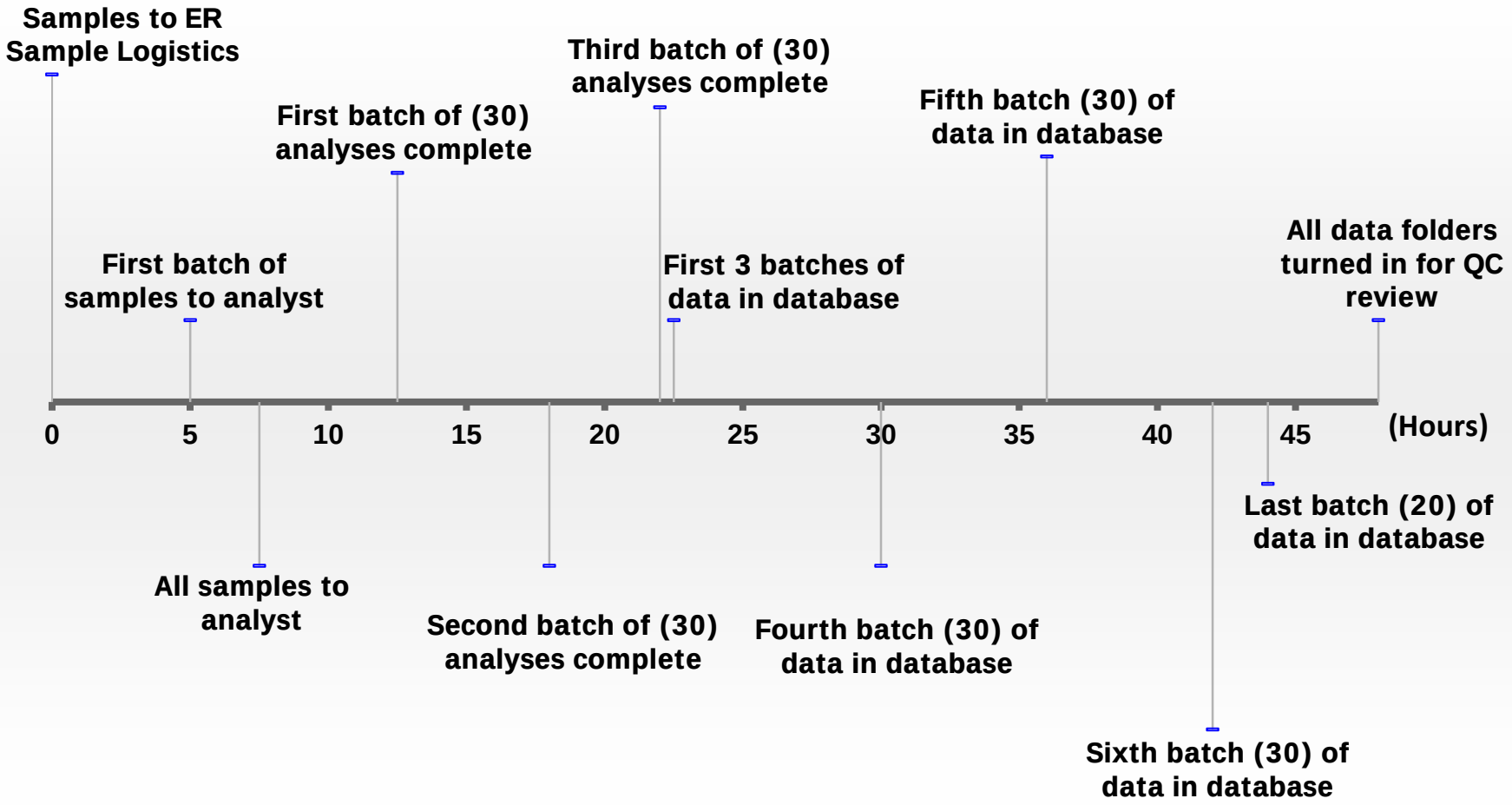
Issues/Lessons Identified (continued)

- Data for the 6th batch of Pu-239 samples included the wrong sample IDs. Analyst corrected this first thing the next morning.
- Gross Beta Screen and Sr-90 analysis results were processed by hand entry of raw output to pre-configured calculational spreadsheets, and there were problems uploading the data.
- Gross Beta and Sr-90 final reports and folders were initially in the wrong format.
- Creatinine QC drifted and failed at the end of an early batch. Analyst decided to run groups of 50 instead of 100.
- Creatinine instrument had an Analyzer Controller Hardware Problem. Roche guided the analyst through fixing it. (<1 hour down time).

Timelines

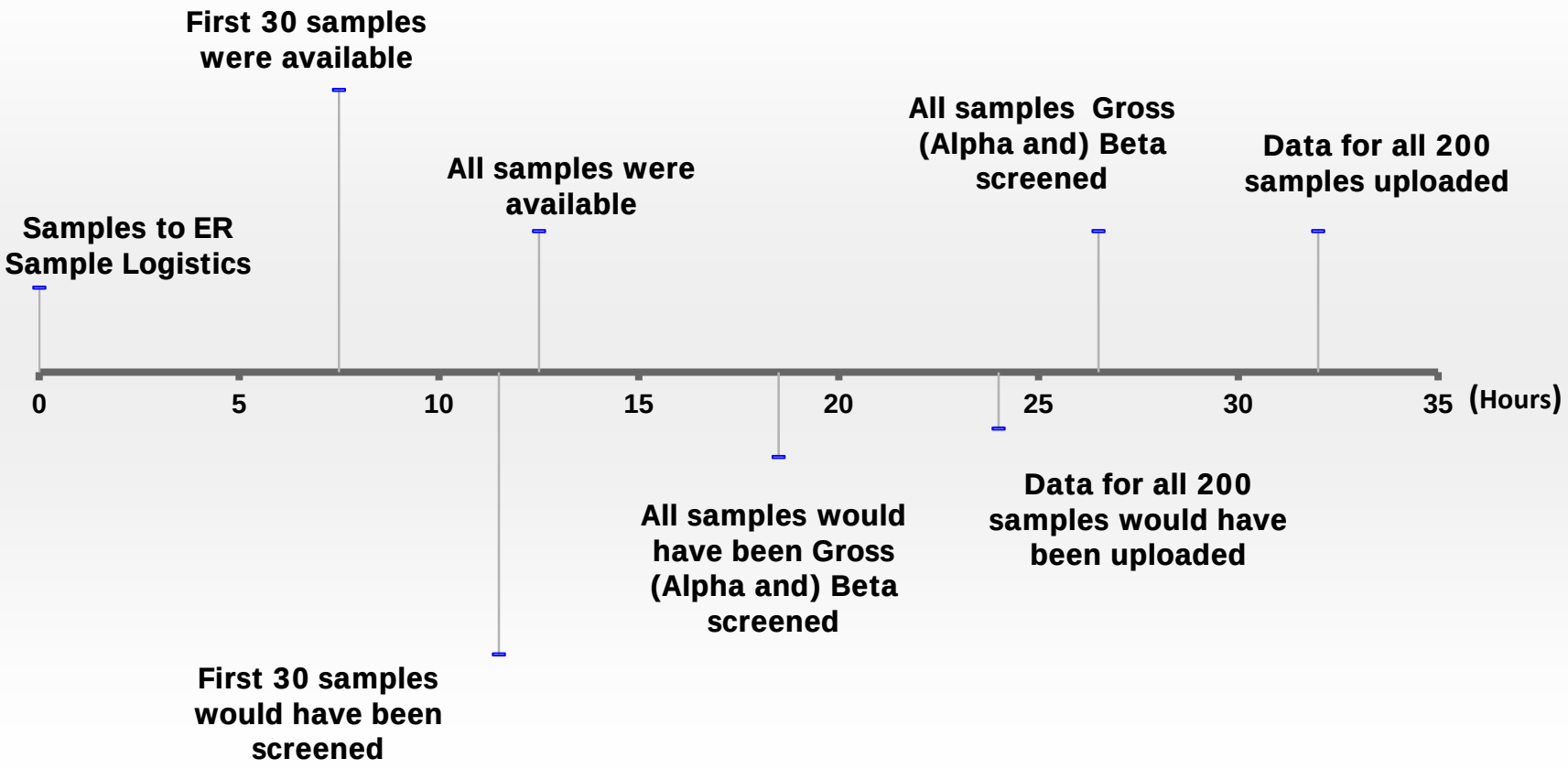
- Note that these timelines are based on work hours.
- We did not work overnight or on weekends (though we did work late).
- Our Gross α/β and Sr-90 analyst was out, and though we trained other analysts to do these analyses, we decided to wait until she came back.

Pu-239 Timeline



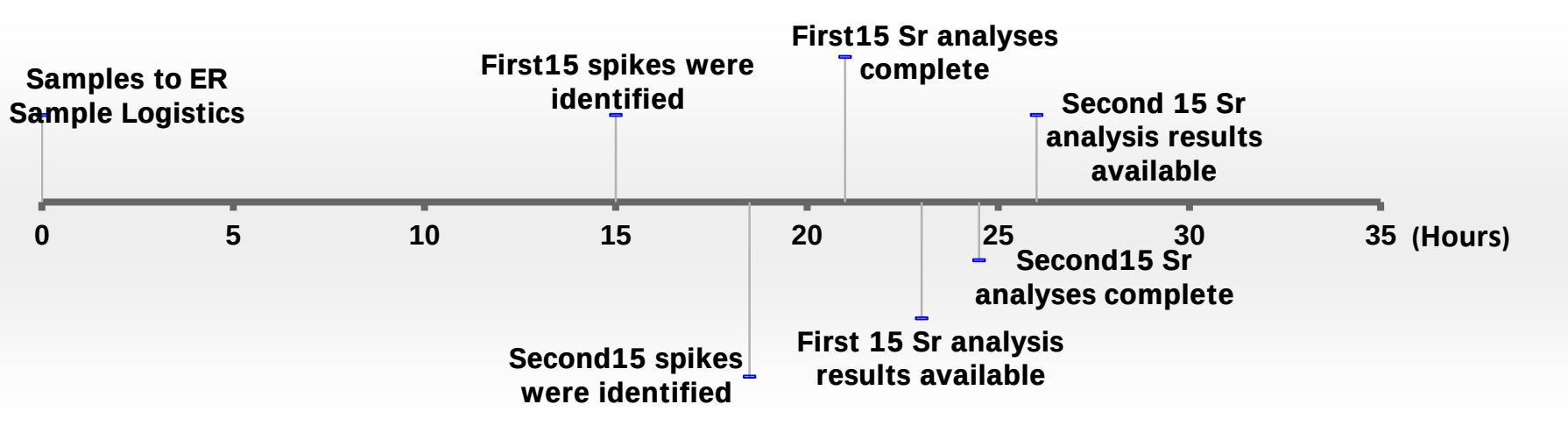
ABOUT 48 HOURS PER 200 SAMPLES

Gross Alpha/Beta Screen Timeline



ABOUT 24 HOURS FOR 200 SAMPLES

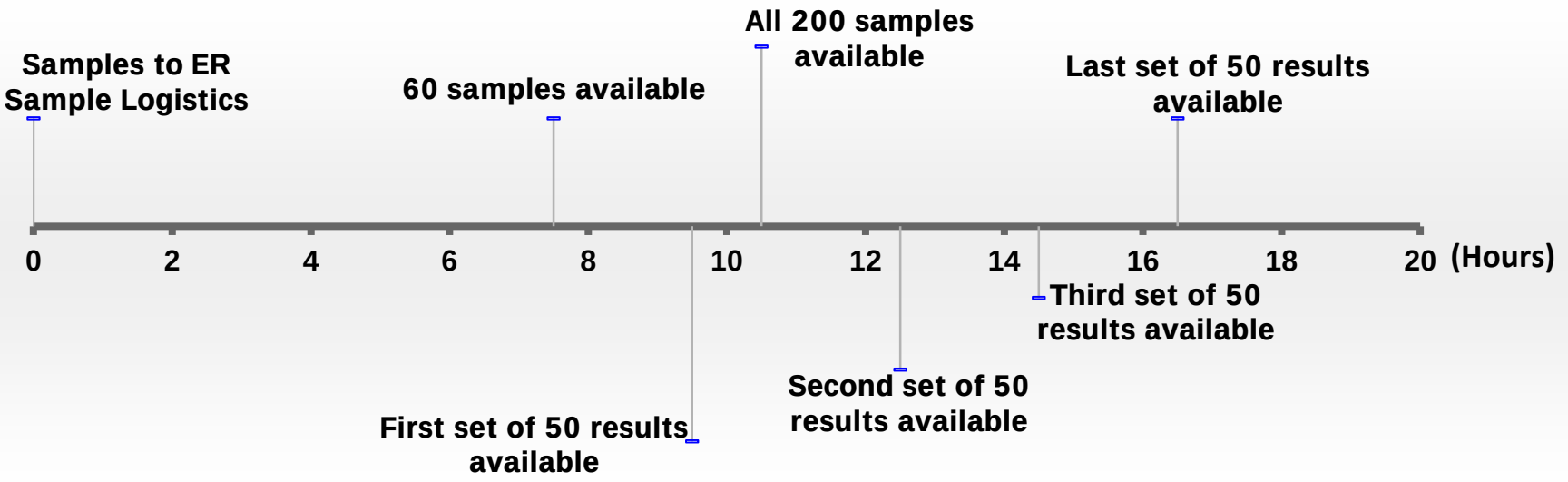
Sr-90 Timeline



- Available data was not in the database, but could have been manually transferred to a report. It was imported to the database much later.
- If we had not used Gross Alpha/Beta Screening, all Sr data for complete Sr analysis of 200 samples would have been available at T_0 + 79 hours (if analyzed serially).
- Cost of columns for 200 analyses would be $4400, vs $660 for 30.

ABOUT 26 HOURS FOR 200 SAMPLES

Creatinine Timeline



ABOUT 16 HOURS FOR 200 SAMPLES

Reporting

- Reporting is to be in coordination with the other participating ICLN agencies/laboratories, and has not yet occurred.

Exercise Timeline "Take-aways"

- Manual aliquoting took a significant amount of time (7.5 to 12.5 hours).
- We can Gross Alpha/Beta screen 200 urine samples in 24 hours.
- We can identify and quantify Pu-239 in 200 urine samples in 48 hours.
- In conjunction with Gross Alpha/Beta screening, we can identify and quantify Sr-90 in 200 urine samples (at a 15% positive Gross Alpha/Beta rate) in 26 hours.
- Gross screening prior to Sr-90 analysis can save a significant number of personnel hours and significantly reduce supply costs.

True Emergency Timeline Modifiers

- In a real emergency we will have access to at least 40 sample logistics staff, rather than just 2, and probably use auto-aliquoters.
- Additional analysts and 4 more high capacity instruments should allow 400-500 Gross Alpha/Beta analyses in 24 hours.
- Additional analysts and 2 more Thermo Element SF-ICP-MS instruments should allow 300 Pu-239 analyses in 24 hours.
- Additional analysts, 6 more SPE processing stations, and 4 more high capacity beta analysis (LSC and GFPC) instruments should allow Sr analyses of 400-500 Gross Alpha/Beta screened samples at a positive rate of 35 to 45%.

Summary

- CDC realized most of its stated goals for participating in this "Confidence Building Competency Test" (CBCT).
- CDC's methods were effective in identifying and quantifying the radionuclides of interest.
- CDC determined that it can perform these analyses on 200 samples in 1 to 2 days.
- A number of issues were identified that can be used to improve performance in these and other methods and future exercises or responses.

Questions - Discussion

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