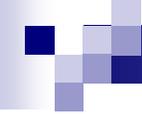


Impact of Medical Test Site (MTS) Law on Laboratory Quality

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History and Background of MTS

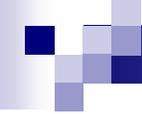
- May 1989 – Washington stakeholders lobbied for state run program
- WA State legislature passed Medical Test Site Law to allow the state to regulate clinical laboratory testing
- October 1990 – MTS rules adopted and implemented; first licenses issued and surveys began in 1991

History (continued)

- September 1992 – CLIA regulations passed
- October 1992 – WA applied for exemption from CLIA
- October 1993 – WA was 1st state granted an exemption from CLIA

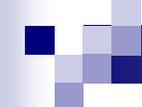
Currently have:

- 3,105 Licensed Laboratories
- 1444 Waived
- 947 PPM
- 171 Accredited
- 533 MTS Inspected laboratories
- Laboratory Categories and Fees the same as CLIA



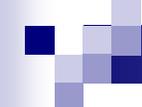
TOP DEFICIENCY

- Deals with competency and training of all laboratory personnel from the director down to the testing personnel
- Majority of lab testing only requires personnel to have a high school diploma with on-site training
- Problem is increased by constant turnover of staff and an aging technical staff that is retiring



Education is Key to Good Performance

- Prior to the start of MTS inspections we gave many training classes
- Continue to give the regulatory piece of many classes given by State PHL and at professional meetings
- Publish *Elaborations* Newsletter monthly that goes to all labs in the state



Coordinate Clinical Lab Advisory Council

- Established in 1994 so that laboratories would have input into our State Healthcare Reform Bill
- Development of 24 Laboratory Practice Guidelines for Providers that are updated annually
- Representation by all lab types and organizations



Internal Quality Improvement Program (QIP)

- Started in 1994 and developed 26 different indicators monitored quarterly
- Every SOD is reviewed for correct citation and inspection consistency
- Surveyor Training and Continuing Education required
- Proficiency Testing Monitored



QIP continued

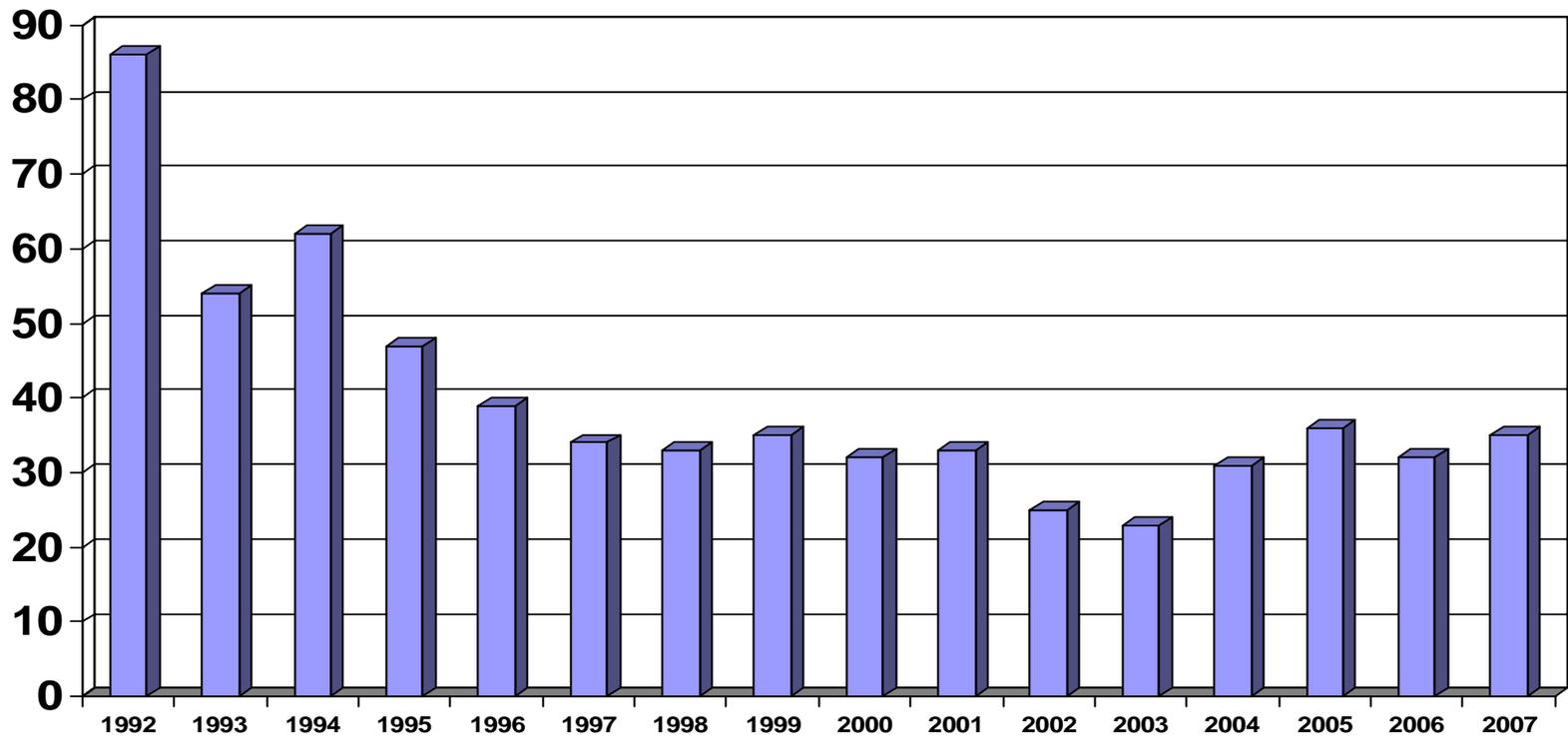
- Surveyors must meet survey goals and timeframes
- Budget goals met
- Data entry is complete and accurate
- Complaint Timeframes met



QIP continued

- Satisfaction Survey sent to labs concerning their survey
- MTS Program reviewed annually by CMS
- Numbers and types of Deficiencies tracked

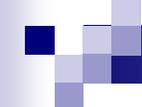
Percent of labs with deficiencies





Quality Improvement Indicator

- What can we do to decrease the number of deficiencies or number of labs with deficiencies?



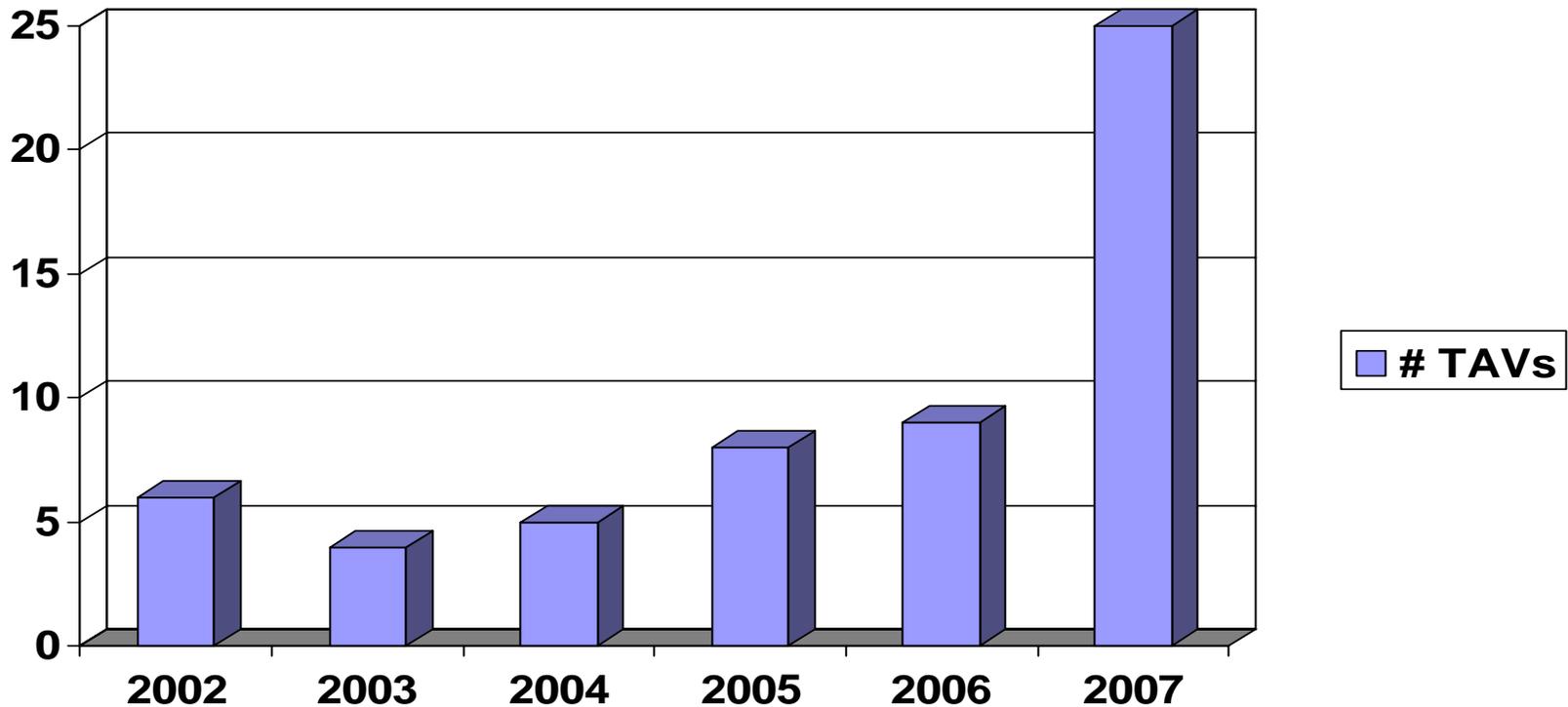
Technical Assistance Visits- TAV

- All new regulated labs are given the opportunity to have a TAV
- Done within first 2 months of receiving a regulated license
- No additional Charge
- Process caught 3 shell labs in 2007
- Did study to see if improved outcome

TAVs Do Improve Outcome

2004-3 rd quarter of 2007	Had TAV (n=23)	No TAV (n=88)
No deficiencies at initial survey	78%	66%
Deficiencies at initial survey	4%	34%
> 5 deficiencies at initial survey	0%	8%
Closed or downgraded	17%	0%

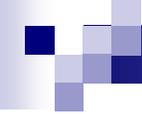
Increased Number of TAVs





Additional Monitors Investigated

- Labs with repeat deficiencies
- Does performing an on-site follow-up improve compliance?
- Does requiring a lab to hire a technical consultant improve outcome?
- Does requiring a director to obtain further training improve outcome?



What Does the Future Hold?

- With the addition of a few more analytes to the CLIA Waived List, we could potentially be back at pre-CLIA oversight levels in POLs

FUTURE?

- More *Elaboration* articles for the Waived and PPM laboratories
- Every new Waived and PPM lab gets a handout on Good Lab Practices
- More training classes for Waived and PPM labs

