New York State Department of Health Hospital Compliance Review Working Hours & Conditions of Post-Graduate Trainees

Triennial-2 Report

April 1, 2013 – March 31, 2016

June 30, 2016

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1.0 PROGRAM SUMMARY

New York State continues to be a leader in work hour requirements and monitoring of compliance with those requirements (NYCRR 405) for approximately 15,000 of the nation's 100,000 Post-Graduate Trainees (PGT). In conjunction with the New York State Department of Health (DOH), IPRO has successfully conducted compliance assessments for the past fourteen years.

This report reflects program operations for the period April 1, 2013 to March 31, 2016, the second triennial monitoring cycle. The current requirements for program operations are:

- Onsite compliance reviews to monitor compliance with requirements for work hour limitations and post-graduate supervision provisions to be conducted every third year (or approximately 30 onsite compliance reviews each year).
- Written assessments using a standardized assessment document for facilities not subject to a triennial onsite compliance review and for facilities with ten or less trainees (approximately 88 per year).
- Onsite complaint investigation and revisits.
- Facility training initiatives.
- Development and implementation of a standardized written compliance assessment document for review of facilities not subject to an onsite visit.
- Development and implementation of onsite survey protocols for reviewing compliance with work hour and supervision requirements.
- Compilation and analysis of findings.
- Preparation of findings for DOH review.
- Monitoring of corrective action plans.
- Support of the DOH enforcement activities (summary of findings and testimony/expert witness for hearings).
- Development and maintenance of logs, statewide and regional database and tracking system for Program operations.
- Development of management reports, including statewide/regional findings, hospital specific reports and quarterly and annual reports.
- Ongoing quality review monitoring, including timeliness of conducting reviews, timeliness of submitting surveillance findings to the DOH for approval, credibility of findings and provider feedback.

1.1. Report Requirements – Contract vs. Triennial Years

The activity and reporting requirements are complex due to the difference between the 12-month periods within the contract and the 12-month periods within the triennial review requirements, as illustrated in Exhibit 1: Contract Year vs. Triennial Review Year Periods.

Exhibit 1: Contract Year vs. Triennial Review Year Periods

The transition to reporting on the new requirements implemented April 1, 2010, necessitated changes in the information included in the annual reports.

Under contract years 1-8, 100% of facilities were reviewed each year and annual results were presented as whole numbers as well as percentages of the whole. For example, if 10% of the facilities reviewed resulted in findings of non-compliance, the reports included that percentage as a percentage of all facilities. Under the new requirements, facilities are reviewed only once every three years and the facilities to be reviewed are selected using a variety of factors that do not permit extrapolation of the findings to the universe of all facilities for any given 12-month period during the triennial review. Additionally, facilities are not subject to a triennial review if they have ten or less trainees. Therefore, if 10% of the facilities reviewed under the new schedule resulted in findings of non-compliance for a particular review year, this percentage could not be reported as representative of the entire universe of facilities. It could only be presented as 10% of the facilities reviewed, with no attribution of that finding to the universe.

For this reason, in the annual reports for contract years 9 through 14, the findings have been presented with the stipulation that the data applied only to the facilities reviewed during that 12-month timeframe. The results in this report, however, include the cumulative results for all facilities over the three-year triennial period (April 1, 2013 – March 31, 2016) and these results can now be compared to the first triennial cycle, as well as to prior contract years that have also consisted of a full survey cycle of all facilities (contract years 1-8).

2.0 Reviews and Investigations

2.1. Compliance Assessments

A total of 342 compliance assessments were conducted in the triennial review period of the contract from April 1, 2013 to March 31, 2016, specifically:

- Ninety-three (93) triennial onsite compliance assessment visits.
- Seventeen (17) onsite revisit assessments.
- One (1) onsite complaint investigation.
- Two hundred thirty-one (231) written (off-site) assessments.

This total reflects the program changes in the April 2010 contract which include: (a) triennial onsite visits for teaching hospitals with more than ten post-graduate trainees, (b) focusing on the working hours and conditions of post-graduate trainee (PGT) levels 1-3, (c) overall assessment of PGT access to and the quality of supervision provided by supervising physicians, and (d) written off-site compliance assessments submitted by facilities during the off years when an onsite visit is not conducted and for facilities with ten or fewer PGTs.

In total, 5,438 PGTs in the State were interviewed during this timeframe to assess compliance with working hour requirements. Upon completion of each facility survey, a letter of findings was issued with a compliance determination. Non-compliance with current requirements was reported to facilities in a statement of deficiencies (SOD) by the DOH. All facilities with documented deficiencies were required to submit a plan for implementing corrective action. All facilities that submit a plan of correction (POC) are assessed for implementation and compliance with their submitted POC at their next visit.

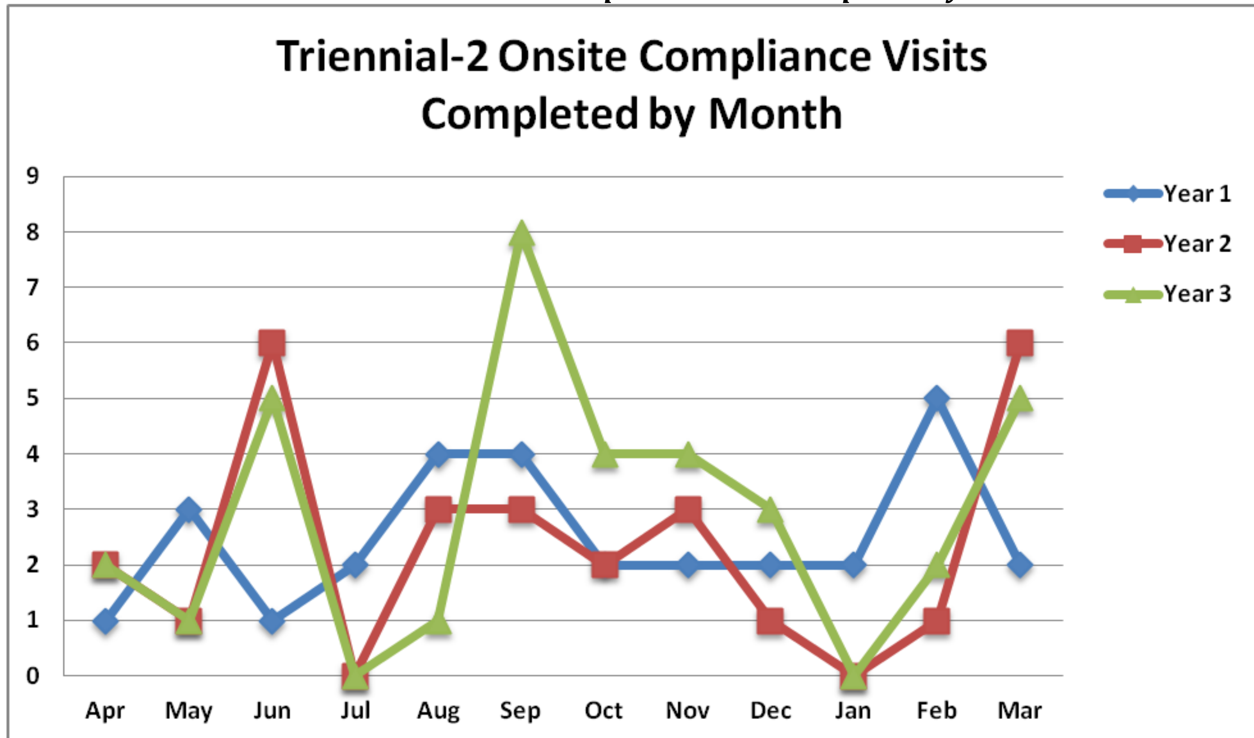
Two hundred thirty-one written (off-site) assessments were conducted for facilities not subject to a triennial visit and facilities with ten or less post-graduate trainees. Letters of closure are sent to the facility upon acceptance of the submitted documentation.

2.1.1. Implementation

Onsite surveys were spread throughout each year of the triennial cycle by region, with a mix of small (<80 residents), medium (81-200 residents) and large facilities (>200 residents). An average of three triennial onsite surveys and seven off-site compliance assessments were planned each month. Adjustments were made as needed to allow for facility and/or program closures, expansions, mergers, etc. To account for those facilities that may have changed during the triennial period (i.e., closed), data reflects all facilities that were subject to review during the triennial period. Of the total 109 teaching facilities identified for the triennial period, 93 received onsite surveys and up to 23 per year (numbers fluctuated throughout the three years) had ten or less PGTs and were not subject to onsite surveys. Of note, for six weeks during October and November 2014, surveys were suspended at the request of the DOH due to Ebola Preparedness activities.

Exhibit 2: Triennial Onsite Compliance Visits Completed by Month, shows the distribution of the 93 onsite reviews that were completed (conducted and analyzed) by month for each year of the triennial cycle.

Exhibit 2: Triennial Onsite Compliance Visits Completed by Month



Data is collected and reported by region, by bed size and by program size. The five regions include the counties/boroughs where teaching hospitals are located, as shown in Exhibit 3: Distribution of Facilities* by Region. The distribution of facilities by bed size and by program size are shown in Exhibit 4: Distribution of Facilities* by Bed Size and Exhibit 5: Distribution of Facilities* by Program (# of PGTs) Size respectively. The facilities included in Exhibits 3, 4, and 5 are those that were subject to an onsite triennial compliance visit.

Exhibit 3: Distribution of Facilities* by Region

Region	Counties/Boroughs with Teaching Hospitals	# of Facilities
Central	Broome, Jefferson, Oneida, Onondaga	7
Lower Hudson Valley & Long Island (LHVLI)	Nassau, Rockland, Suffolk, Ulster, Westchester	22
Northeast (NE)	Albany, Clinton, Otsego, Schenectady	4
New York City (NYC)	Bronx, Kings, New York, Richmond, Queens	46
Western	Cattaraugus, Erie, Monroe, Niagara, Steuben	14
TOTAL		**93**

Exhibit 4: Distribution of Facilities* by Bed Size

Bed Size Categories	# of Facilities
0-200	12
201-400	38
401-600	28
600+	15
TOTAL	**93**

Exhibit 5: Distribution of Facilities* by Program (# of PGTs) Size

Program Size Categories	# of Facilities
11-80	40
81-200	20
201+	33
TOTAL	**93**

* *Facilities subject to onsite triennial survey*

The distribution of the onsite assessments relative to the universe of 93 facilities eligible for a triennial onsite survey is shown in Exhibit 6: Onsite Visits by Region by Year, Exhibit 7: Onsite Visits by Bed Size by Year, and Exhibit 8: Onsite Visits by Program Size by Year.

Exhibit 6: Onsite Visits by Region by Year

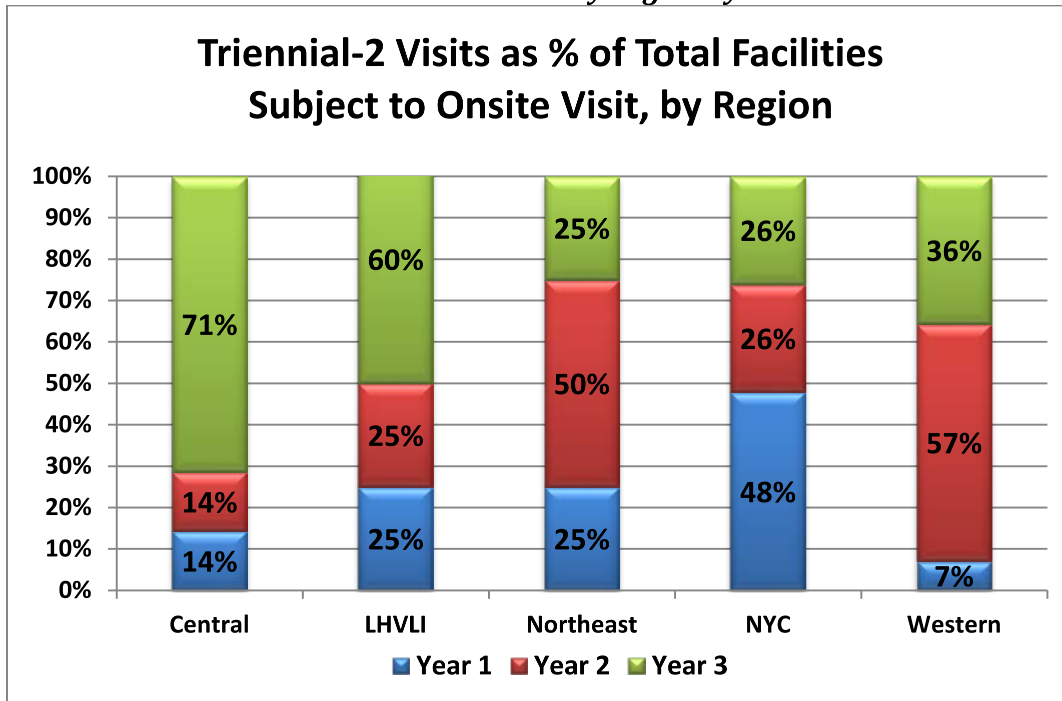


Exhibit 7: Onsite Visits by Bed Size by Year

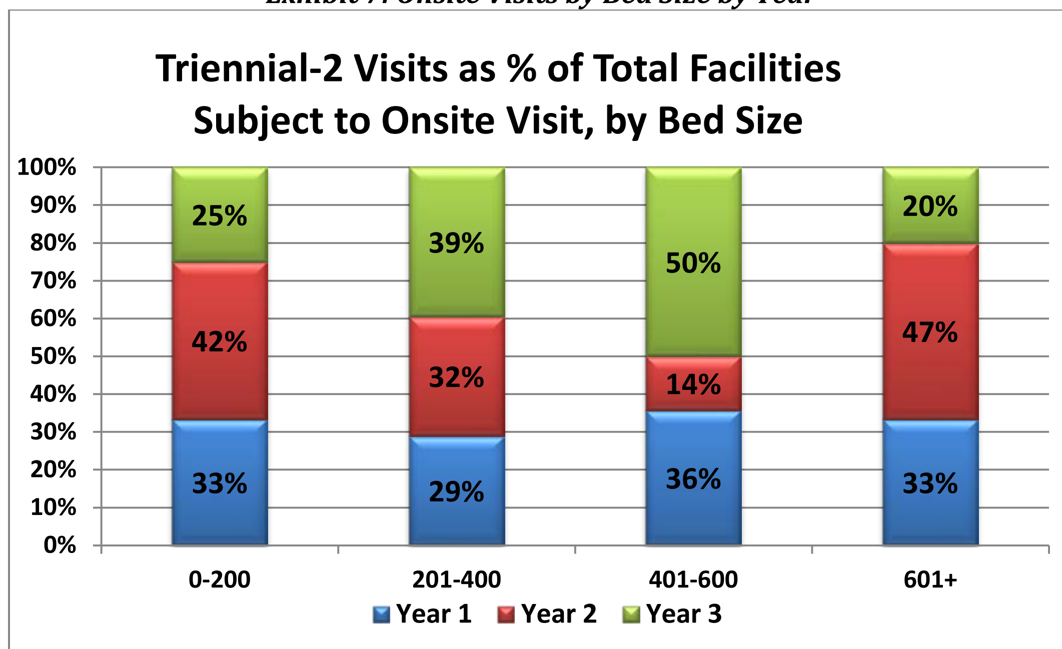
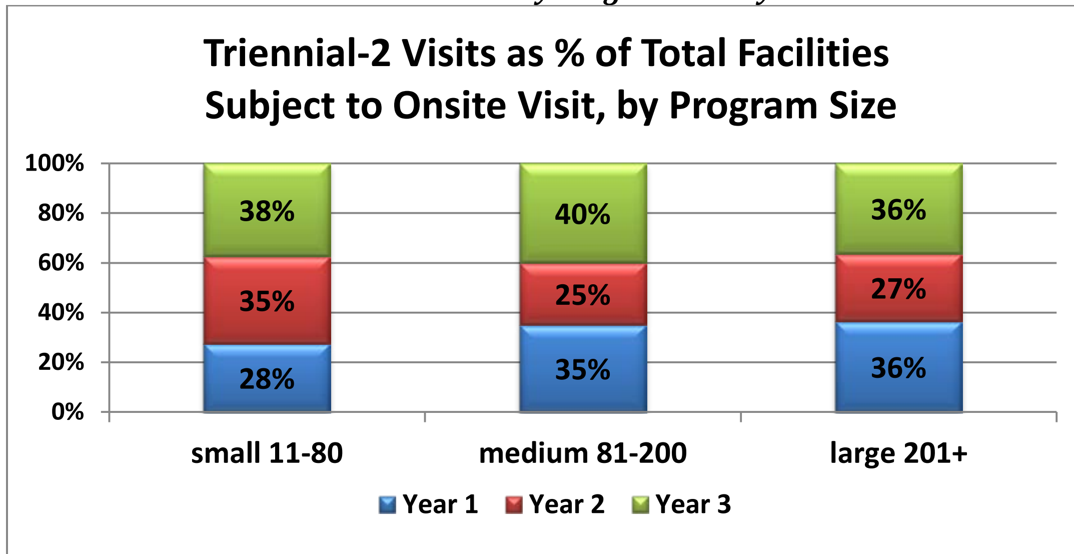


Exhibit 8: Onsite Visits by Program Size by Year



2.1.2. Distribution of Findings

Ninety-three (93) triennial compliance visits were conducted under the terms of the contract, where each teaching facility with more than ten residents receives an onsite compliance visit once in three years. Of these, 12 evidenced some level of non-compliance at the time of the onsite review resulting in a citation.

Exhibit 9: Triennial Compliance Assessment—Statewide Results, and Exhibit 10: Triennial Compliance Assessment—Results by Region, show the distribution of the 93 triennial reviews, by compliance and non-compliance on a statewide and regional basis respectively. For reporting purposes, non-compliance means that one or more deficiency/finding was identified during the onsite review. Each deficiency/finding cited could result from an issue associated within one or more programs within the facility.

Exhibit 9: Triennial Compliance Assessment—Statewide Results

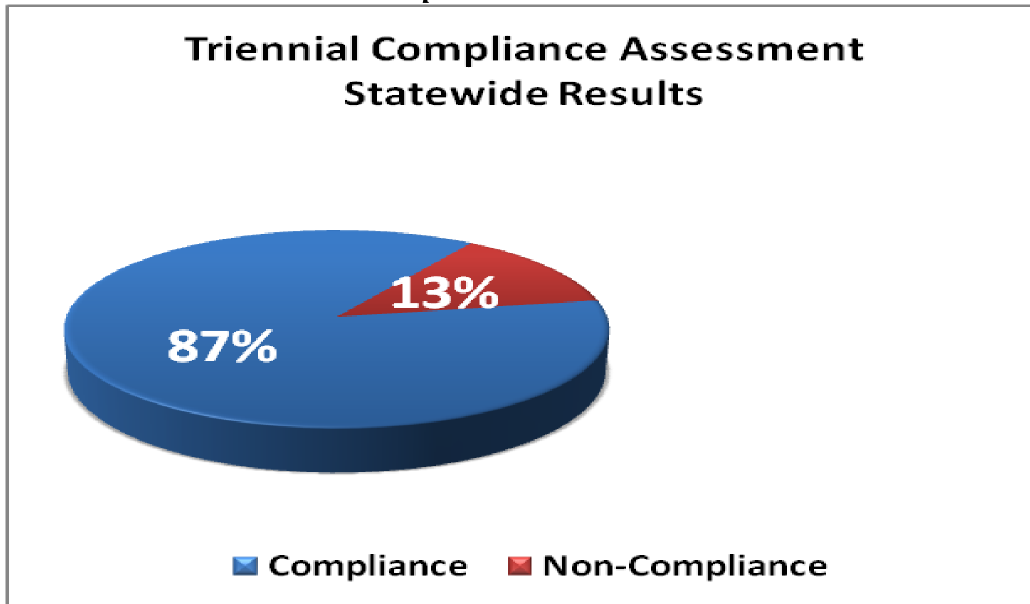


Exhibit 10: Triennial Compliance Assessment—Results by Region

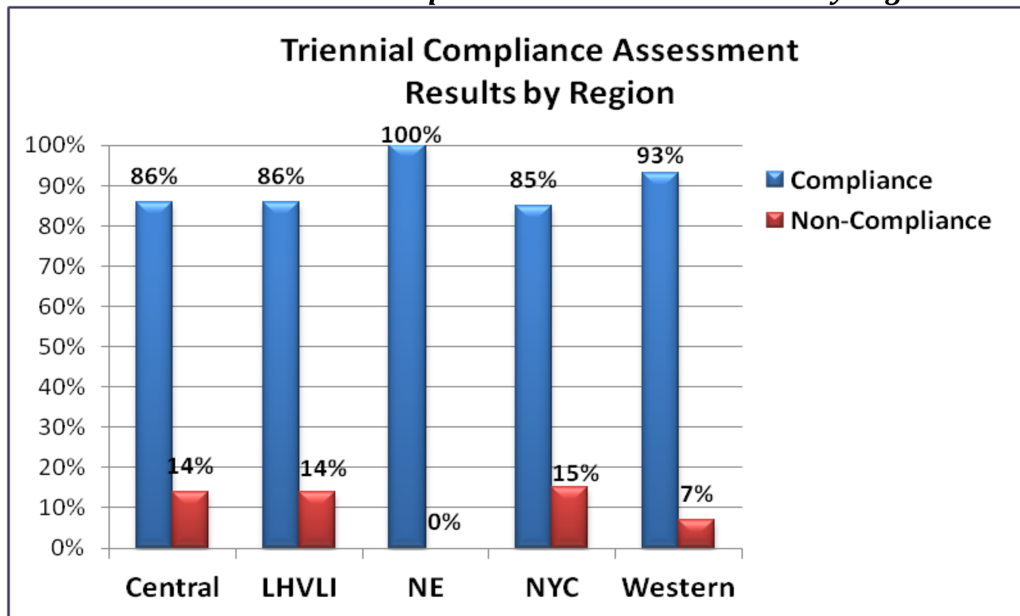


Exhibit 11: Triennial Compliance Visits and Citations by Month, illustrates the distribution of the 93 triennial visits compared to the findings of non-compliance for visits completed each month. Consistent with previous years' findings, it does not appear that survey outcome was significantly influenced by survey scheduling. While it is recognized that throughout the year there are dates and periods of time where routine scheduling for hospitals may be more difficult, compliance surveys continue to be scheduled throughout the full contract cycle.

Exhibit 11: Triennial Compliance Visits and Citations by Month

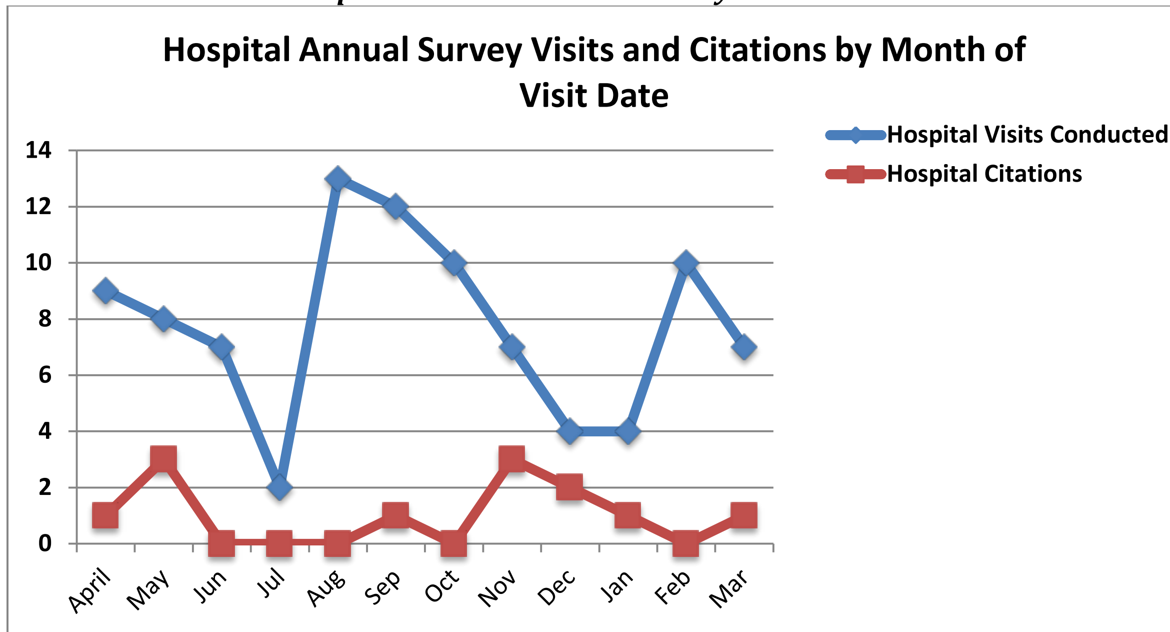
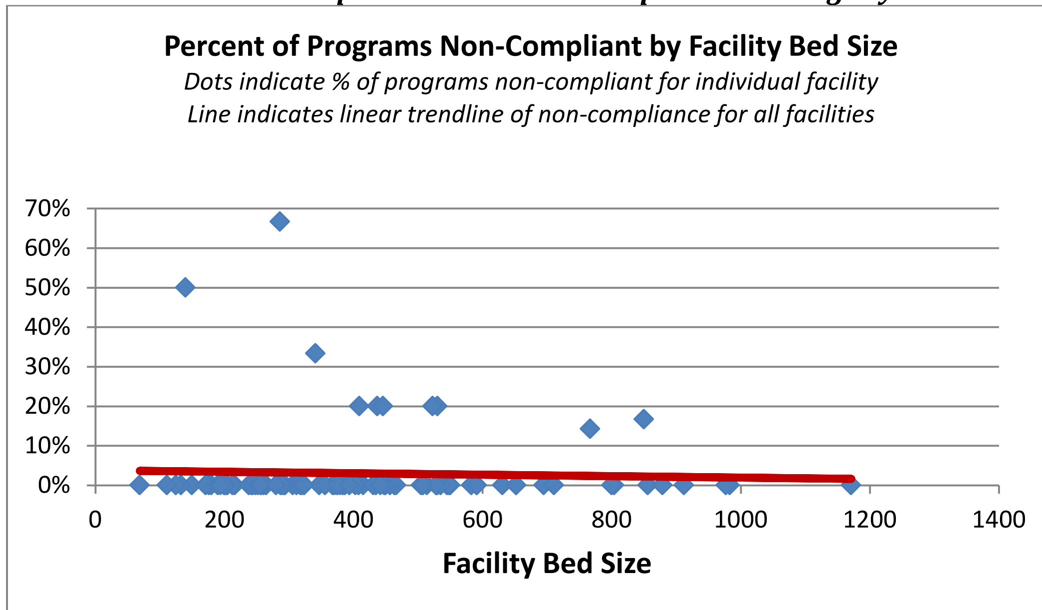


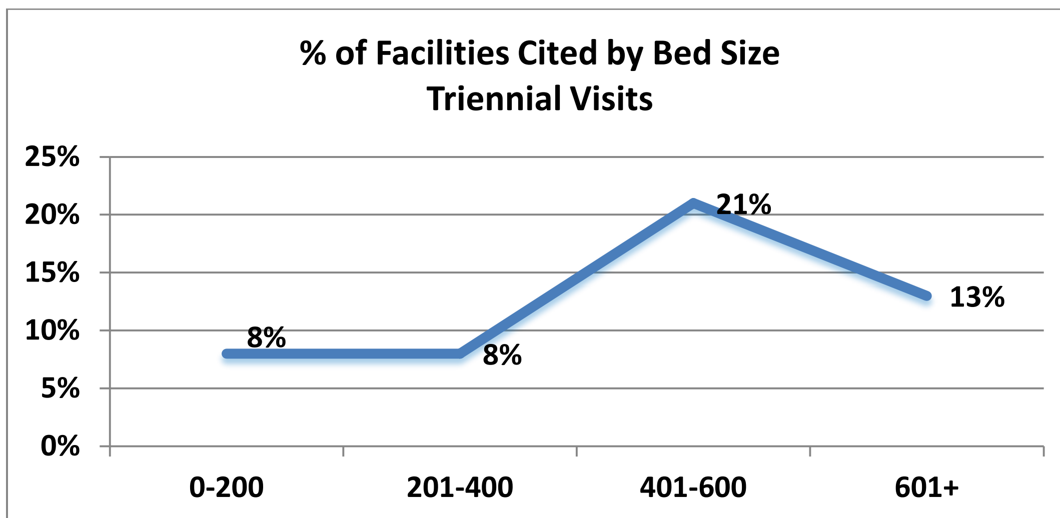
Exhibit 12: Triennial Compliance Visits-Non-Compliance Findings by Bed Size, presents a detailed assessment of compliance by bed size for the 93 triennial visits. Each facility is identified by its bed size, and is evaluated by the percent of non-compliance, as evidenced by the percentage of facility programs that were cited for non-compliance. For example, a facility review that included four teaching programs, surgery, internal medicine, OB/GYN, and pediatrics, and was found out of compliance in only one program, would be out of compliance for 25% of the programs reviewed. For analysis purposes, all sub-specialties were included under the primary program category.

Exhibit 12: Triennial Compliance Visits-Non-Compliance Findings by Bed Size



None of the triennial visits conducted evidenced non-compliance in every teaching program reviewed at that site. Another illustration of this relationship is seen in Exhibit 13: Triennial Compliance Visits-% of Facilities Cited by Bed Size.

Exhibit 13: Triennial Compliance Visits-% of Facilities Cited by Bed Size



2.2. Summary of Findings

2.2.1. Summary of Findings—Onsite Compliance Reviews

During the triennial review cycle, 93 triennial visits, 17 revisits and one (1) complaint investigation were conducted for a total of 111 onsite visit types. Of these, 12 facilities evidenced some level of non-compliance with requirements for resident working hours and conditions. Citations were issued for 12 triennial visits and two (2) revisits. The complaint review was not substantiated. Compliance findings for the 93 triennial visits include the following:

- Eighty-one hospitals were found in substantial compliance with requirements, with no citations issued;
- Twelve hospitals were cited for non-compliance in at least one program area:
  - ✓ In eleven of the facilities cited, one program area within the facility evidenced non-compliance with at least one review criteria,
  - ✓ In one of the facilities cited, two program areas within the facility evidenced non-compliance with at least one review criteria,
  - ✓ In four of the facilities cited, one program area evidenced non-compliance in more than one review criteria,
  - ✓ Two facilities were issued a repeat citation for both the triennial and revisit;
- Of the 12 facilities that were cited for non-compliance, 13 total programs were cited with a total of 20 individual citations.

For the 93 triennial visits conducted, specific findings based on current program requirements include:

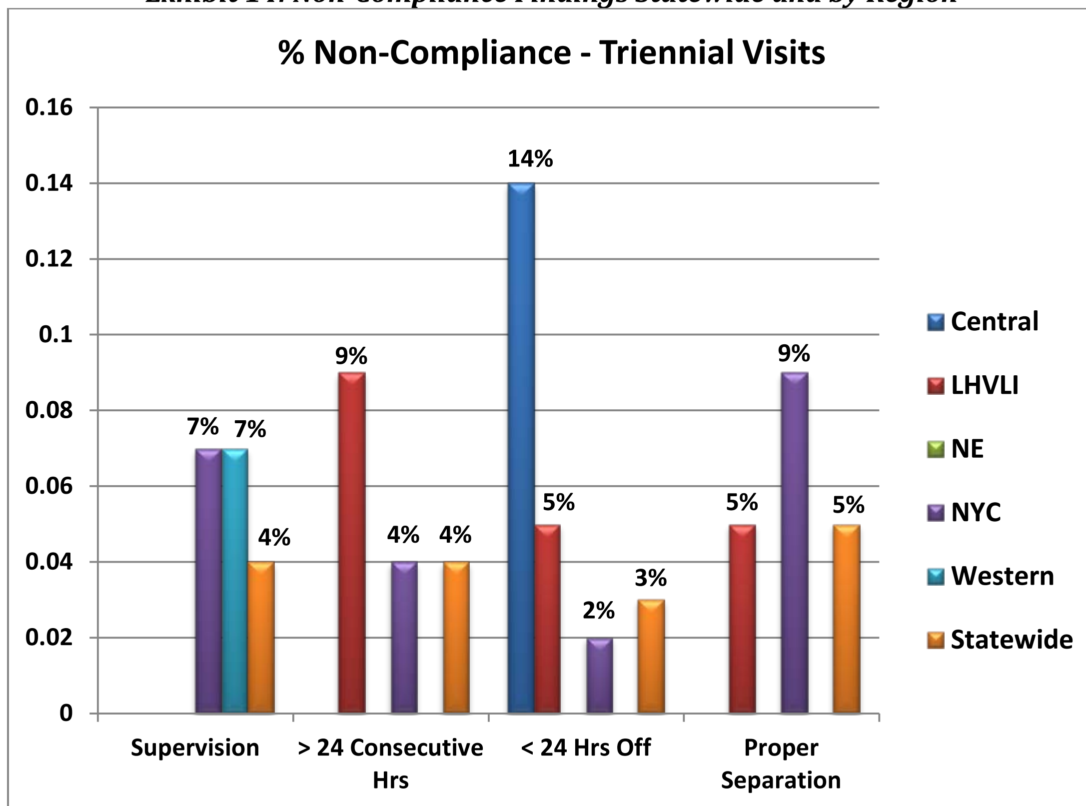
- 80 Hours Per Week. On average, over a four-week period, the work week is limited to 80 hours per week. ***One facility was cited for residents working hours in excess of 80 hours each week.***
- 24 Consecutive Hours. Regulations limit scheduled assignments to no more than 24 consecutive hours. ***Four facilities were cited for residents working more than 24 consecutive hours; one facility was cited for both the triennial and revisit.***
- 24 Hours Off Period. Scheduling must include one full 24-hour off period each week. ***Three facilities were cited for residents not receiving a full 24-hour off period during each week.***
- Proper Separation. Assigned work periods must be separated by not less than eight non-working hours. ***Five facilities were cited for resident work assignments not separated by required non-working time; one facility was cited for both the triennial and revisit.***

- Working Conditions. This category includes, for example, consideration for sleep/rest accommodations, and the availability of ancillary and support services. ***No facilities were cited for failing to meet expected working conditions for residents.***
- Supervision. This category reflects 24/7 access to and availability of the attending physician to provide supervision of all trainees with documented evidence in the medical record. Trainees in their final year or who have completed at least three years of training may perform supervision if it can be demonstrated that the attending is immediately available by phone and readily available in person. For surgical programs, the requirements are personal supervision of all surgical procedures requiring general anesthesia or an operating room, preoperative examination and assessment by the attending physician, and postoperative examination and assessment no less frequently than daily by the attending physician. ***Four facilities were cited for supervision: three for improper medical record documentation of post-graduate trainee supervision with one being a repeat citation, and one for improper onsite supervision.***
- Working Limits. This category reflects documented inconsistencies in working hour information collected during interviews and through observation when compared to a review of documentation. To validate interview data, review staff screen facility documentation not limited to medical records, operative reports, delivery logs, and/or consult logs, to document the date and/or time certain services are provided and recorded. ***None of the visits conducted evidenced violations in this area.***
- QA/QI. Each hospital is required to conduct and document ongoing quality assurance/quality improvement (QA/QI) activities for the identification of actual or potential problems in accordance with requirements set forth in statute. ***No facilities reviewed during this timeframe were cited for deficiencies in their QA/QI performance.*** It should be noted that QA/QI would automatically be cited for any facility that had a repeat deficiency from the prior year or in the case of a same year revisit, a repeat of findings in that year.
- Governing Body. The responsibility for the conduct and obligations of the hospital including compliance with all Federal, State and local laws, rests with the hospital Governing Body. ***During this timeframe, Governing Body was not cited as an area of non-compliance.***
- Moonlighting. Regulations place responsibility with each hospital to limit and monitor the working hours associated with moonlighting or dual employment situations. Trainees who have worked the maximum number of hours permitted in regulation are prohibited from moonlighting as physicians providing professional patient care services. ***No violations pertaining to moonlighting or dual employment requirements were identified.***

- Emergency Department (ED). For hospitals with more than 15,000 unscheduled emergency department visits, the ED assignments of trainees must be limited to no more than 12 consecutive hours. ***No violations were identified for this program area for facilities reviewed during this reporting period.***
- Medical Records. Medical record documentation and authentication regulations require that all medical record entries be signed, dated, and timed. ***No facility was cited for noncompliance with medical record entry requirements.***

The most notable areas of non-compliance findings are illustrated in Exhibit 14: Non-Compliance Findings Statewide and by Region for triennial surveys within each region and statewide.

Exhibit 14: Non-Compliance Findings Statewide and by Region



2.2.2. Supervision

This category reflects 24/7 access to and availability of the attending physician to provide supervision of all trainees with documented evidence in the medical record. Statewide non-compliance was cited in four facilities of the triennial surveys conducted.

2.2.3. 24 Consecutive Hours

New York State regulations limit scheduled assignments to no more than 24 consecutive hours. In applying this standard and for determining compliance, an additional unscheduled transition period of up to three hours may be used by facilities to provide for the appropriate transfer of patient information. Hospitals have some flexibility in using the three-hour transition period to carry out rounds, grand rounds, and/or the transfer of patient information. New patient care responsibilities may not be assigned during the transition period, and the three-hour period, if used, is counted toward the weekly work-hour limit of 80 hours.

Statewide, non-compliance was cited in four facilities of the triennial surveys conducted.

2.2.4. 24-Hour Off Period Per Week

New York State regulations require that scheduling must include one full 24-hour off period each week free from patient care assignments or responsibilities. Statewide, non-compliance was cited in three facilities of the triennial surveys conducted.

While programs may develop schedules that allow for a full weekend off or "Golden Weekend," programs must be mindful that NYS regulations require a 24-hour off period each week, with no averaging. One difficulty that can present itself with using the post-call day as the 24-hour period off is ensuring that there is a full 24 hours off post-call if this is the only day off for the week.

Sick, back-up, and/or jeopardy call, as well as home call systems can also result in non-compliance with the required 24-hour off period per week. Trainees under these call systems need to be available for coverage, and therefore, are not free from all patient care responsibilities even if they are not called back into the facility. If a trainee is scheduled for multiple consecutive days of call (i.e., back-up call every day for one month), the trainee would not have the required 24-hour off period per week.

2.2.5. Proper Separation

New York State regulations require that scheduled on-duty assignments be separated by not less than eight non-working hours. For all surveys conducted this was the most frequently cited area. Statewide, non-compliance was cited in five facilities of the triennial surveys conducted.

2.2.6. Facility Revisits and Monitoring of Corrective Action Plans Results

Seventeen facility revisits involving 20 resident programs were conducted to monitor the facility's plan of correction (POC) implementation for previously identified non-compliance. Specifically:

- Revisits involved one family practice, eight internal medicine, three OB/GYN, one pediatric, and seven surgery programs, within a total of seventeen facilities.
- 88% of onsite revisits evidenced substantial compliance with the POC.
- 12% (2 of 17) were cited for repeat violation at the revisit.

It is noted that there were 18 facilities cited in the first triennial cycle; one of those facilities closed before the end of that triennial cycle and before a revisit was scheduled.

2.2.7. Onsite Complaint Investigation Results

There was one onsite complaint visit conducted during the triennial period. After investigation, the complaint was not substantiated.

2.3. Written (Off-Site) Assessments Results

No concerns were identified for the 231 off-site assessments.

2.4. Ongoing Quality Review Monitoring

IPRO continues to conduct internal quality improvement and monitoring activities inclusive of staff performance, timeliness of all survey activities/processes and inquiries, as well as point-of-service feedback from facilities post-survey. Issues or trends are reviewed and improvements are made as needed to ensure program effectiveness and consistency. All internal timeliness standards and goals were met.

3.0 Facility Training and DOH Support

IPRO continues to provide training and updates as requested by facilities and other collaborators/special interest groups. During the triennial review period, IPRO provided two formal training sessions to facilities and collaborators. IPRO provided several informal training/discussions during onsite survey visits.

IPRO also received and responded to inquiries via telephone calls, emails, and in person regarding the regulations, processes, SOD/POC details, etc., and monitors such communications for trends or actions needed.

4.0 Facility Program Strengths / Best Practices

During the 14 years of IPRO's contract with the DOH, facility strengths and/or changes made in response to and/or to be compliant with duty hours have been tracked. These changes continue to trend around schedule, staffing, and education/procedural changes. The following highlights summarize this triennial cycle:

- ✓ Adjusted hours of morning report and/or post-call residents present cases first.
- ✓ Changed time of morning and/or afternoon sign-outs.
- ✓ Changed/revised time and/or days of on-call shifts, night float, etc. to be in compliance with work hour regulations.
- ✓ Revised rotation changes, such as added, deleted, length of rotation, etc.
- ✓ Use of Hospitalists, Nurse Practitioners and Physicians Assistants for coverage.
- ✓ Added more faculty/attending physician coverage.
- ✓ Re-allocated resources to cover busier services/times.
- ✓ Implemented protected education time.
- ✓ Dedicated a one or two week block solely for clinic scheduling as compared to scattered weekly clinic assignments ("4+1" or "5+2").
- ✓ Availability of conferences and presentations on-line.
- ✓ Use of software for duty hour monitoring.
- ✓ Focus on handoff procedures.

Best practices include:

- ✓ Well written policies that clearly state the work hour regulations and are consistent throughout the organization.
- ✓ Not scheduling to the maximum allowable hours to provide enough flexibility in the schedule to allow for sign-out, transition time, academics, a full day off, etc., while meeting all work hour requirements.
- ✓ Periodically check what hours residents are actually working to ensure the schedule allows for compliance.
- ✓ Monitoring work hours by rotation to include any rotators in from another program.
- ✓ Follow-up on the causes of non-compliance so the appropriate issue can be addressed.

5.0 Continual Improvements

IPRO continues to work with the DOH to identify and implement improvements to the program, including:

- Provided programs with information on how to be in compliance with the NYS 405 code; revised documents posted on IPRO website.
- Revised and distributed Resident Work Hour brochures to PGTs and facilities.
- Monitored survey processes, such as unannounced visits, staggered survey schedule, and site review protocols, as well as tracking and trending of program strengths, survey findings, feedback, and other QA/QI measures.
- Provided onsite educational sessions.

APPENDIX A. ANNUAL OFF-SITE COMPLIANCE ASSESSMENT TOOL

The off-site assessment form that follows is used with facilities that are not subject to a triennial onsite assessment because they have ten or fewer Post Graduate Trainees or because they are not scheduled for a triennial onsite assessment during the contract year.

Annual Off-site Compliance Assessment
Working Hours & Conditions of Post-Graduate Trainees

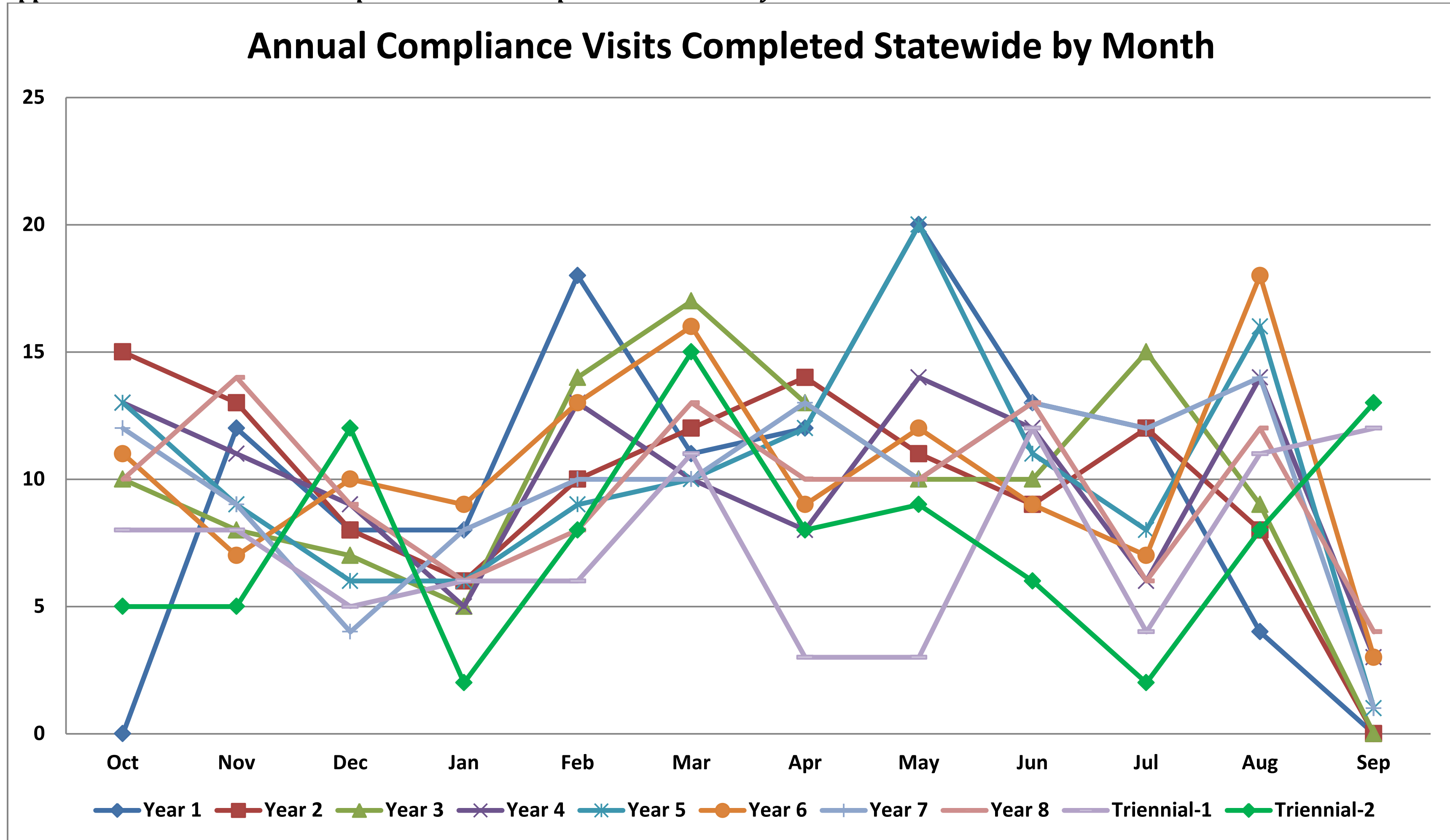
Please submit the following documentation:	
1.	List of all accredited and non-accredited programs that sponsor residents in your hospital.
2.	List of contact personnel (Program Director/Program Coordinator) and telephone number/extension for each department (including subspecialties).
3.	List of all post-graduate trainees by service and PGY level.
4.	Identify the Senior member of hospital administration who has oversight of compliance with work hour rules.
5.	Description of system and/or method for monitoring resident work hour compliance.
6.	Meeting minutes specific to monitoring results, such as GME, departmental, etc. These can be rolled up/summarized or include only sections relevant to working hours.
7.	For the past 12 months, please identify any issue, complaint or finding identified to the facility that raises concerns regarding compliance with work hour rules and/or supervision requirements. Indicate which actions were taken by the facility to review/address concerns raised and/or outcome of allegation.
8.	Indicate if any changes have been implemented in the past 12 months for education, scheduling/staffing, etc. to meet or maintain compliance with work hour rules.
9.	Describe or submit documentation outlining the process for handling internal complaints or concerns regarding resident work hours and/or supervision requirements.
10.	Indicate how you inform residents of an external process / option (such as ACGME, DOH, IPRO, etc.) if they have concerns regarding work hour and/or supervision requirement issues.
11.	Have any educational/ information sessions been held for trainees detailing work hours rules and the impact or effects of sleep deprivation and fatigue on work performance and safety? Please submit dates and agendas (if available).
12.	Any other supporting documentation/ information that you wish to submit for review.
	Note: All information should be submitted in sections that correspond with the number/numbers above. The facility will receive confirmation that information has been received and will be notified if any additional information/documentation is required.

QF-HC-IPRO 05/01/11

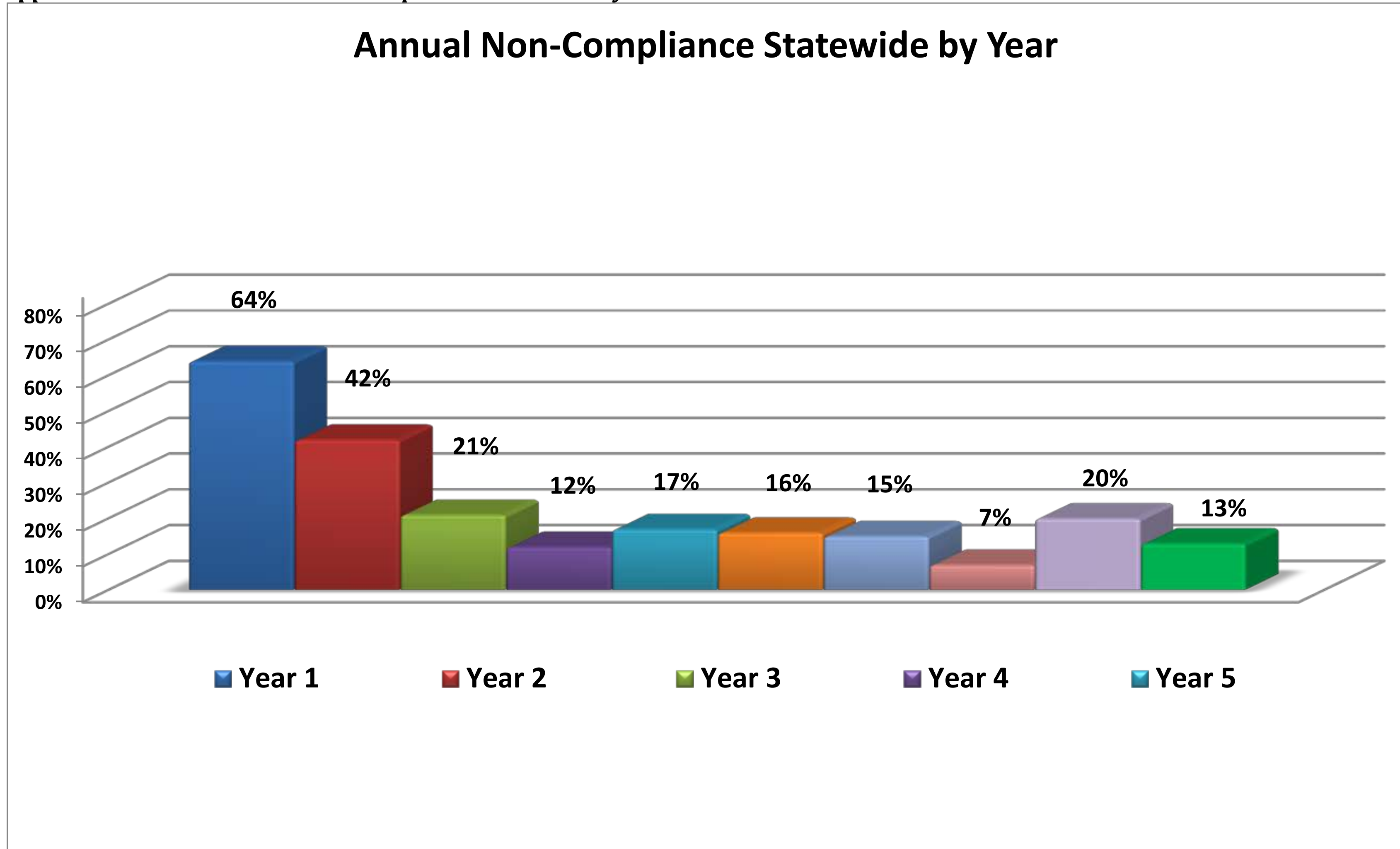
APPENDIX B. ANNUAL COMPARISON CHARTS

On the following pages, a series of charts is presented showing results since the initiation of the program on October 1, 2001. Percentages are based on the total visits conducted per year unless otherwise specified as annual/triennial.

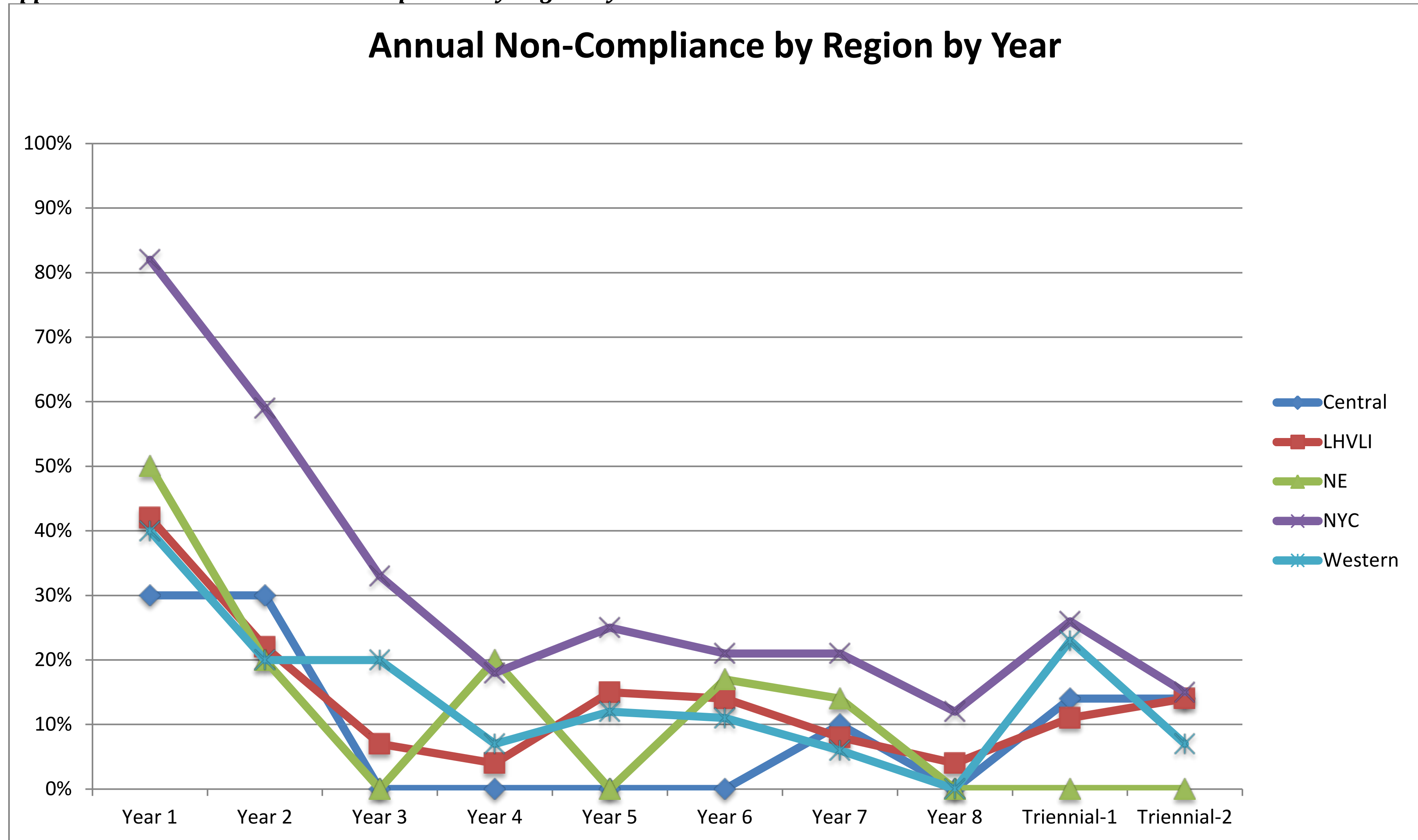
Appendix Exhibit 1: Annual Compliance Visits Completed Statewide by Month



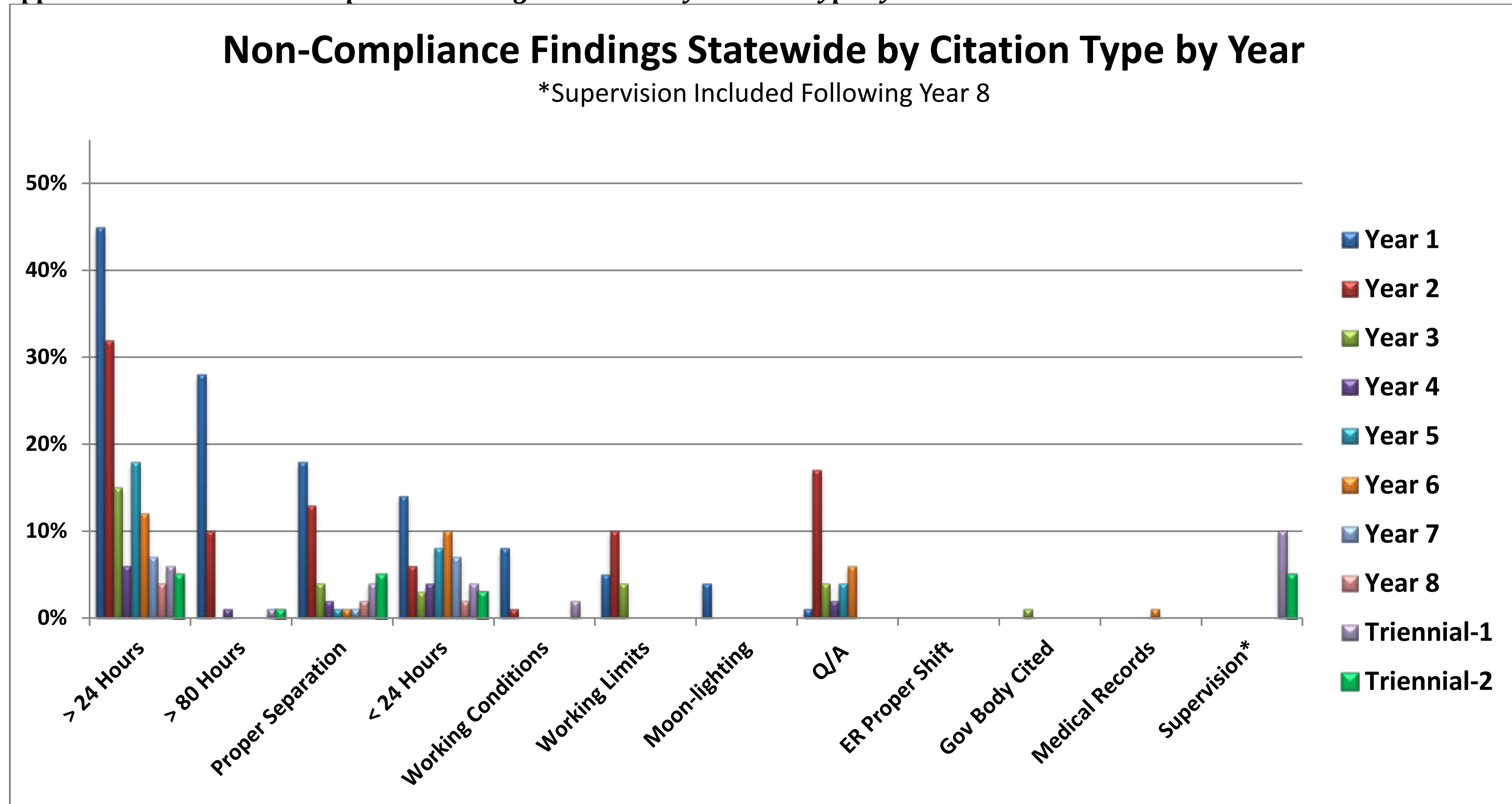
Appendix Exhibit 2: Annual Non-Compliance Statewide by Year



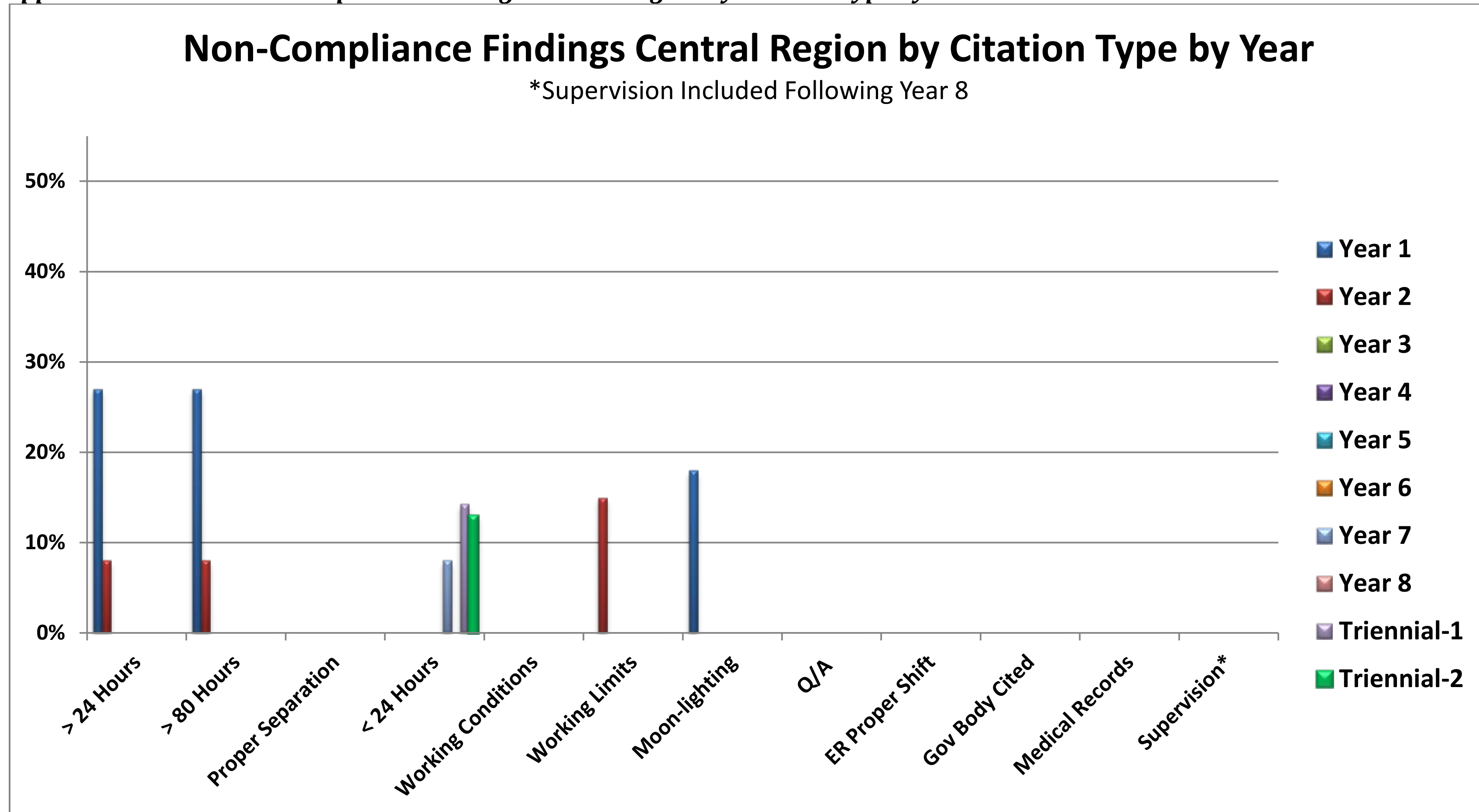
Appendix Exhibit 3: Annual Non-Compliance by Region by Year



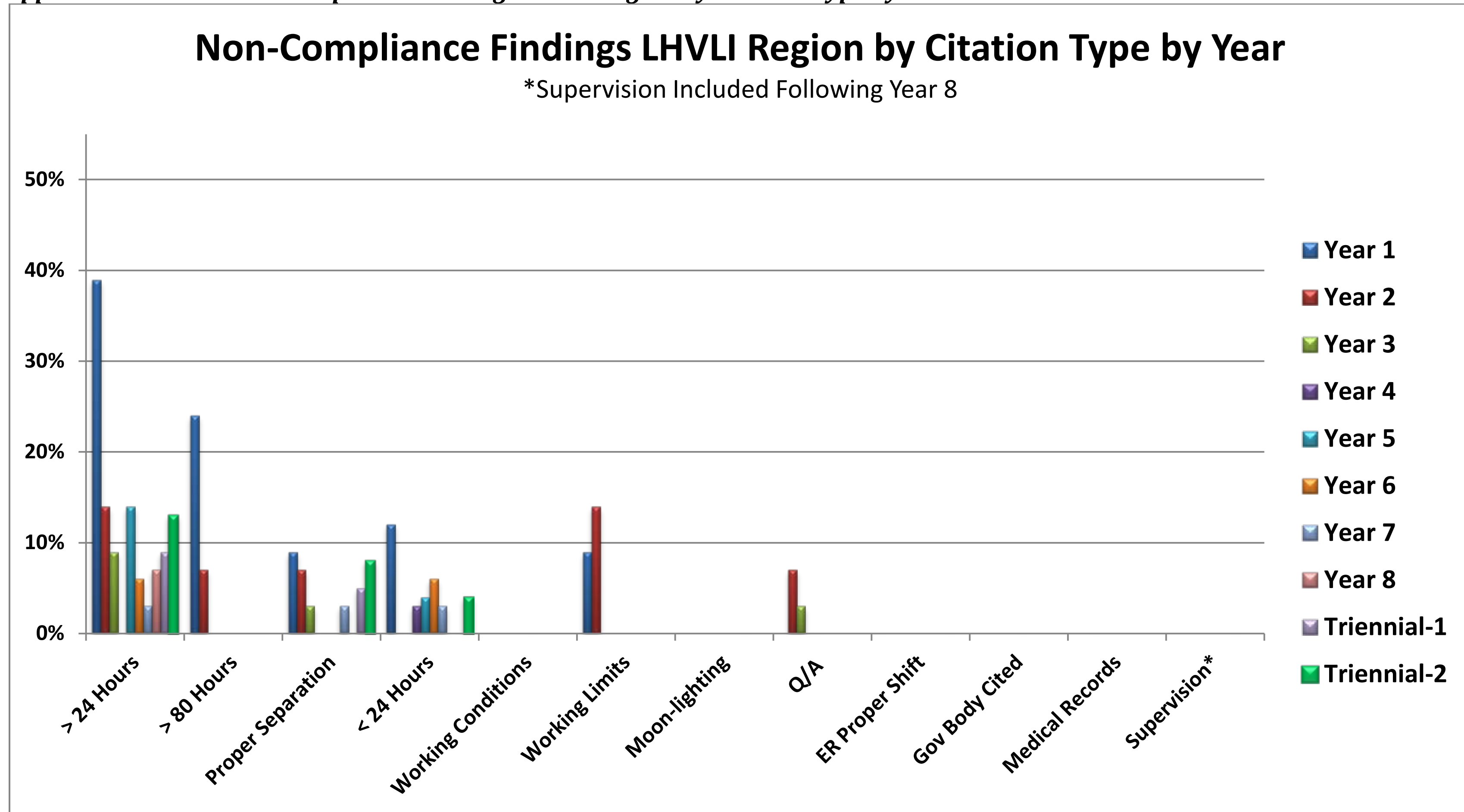
Appendix Exhibit 4: Non-Compliance Findings Statewide by Citation Type by Year



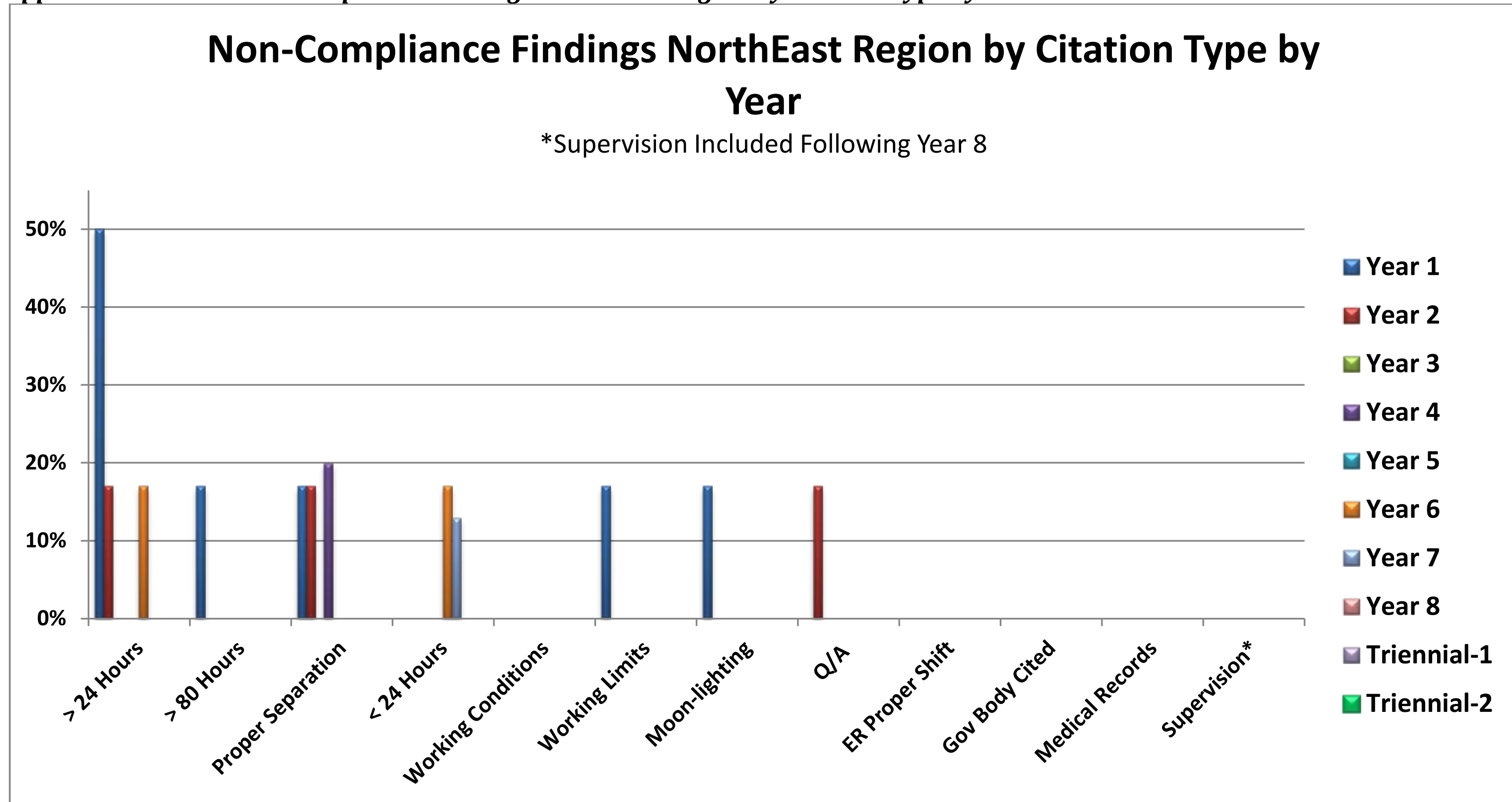
Appendix Exhibit 5: Non-Compliance Findings Central Region by Citation Type by Year



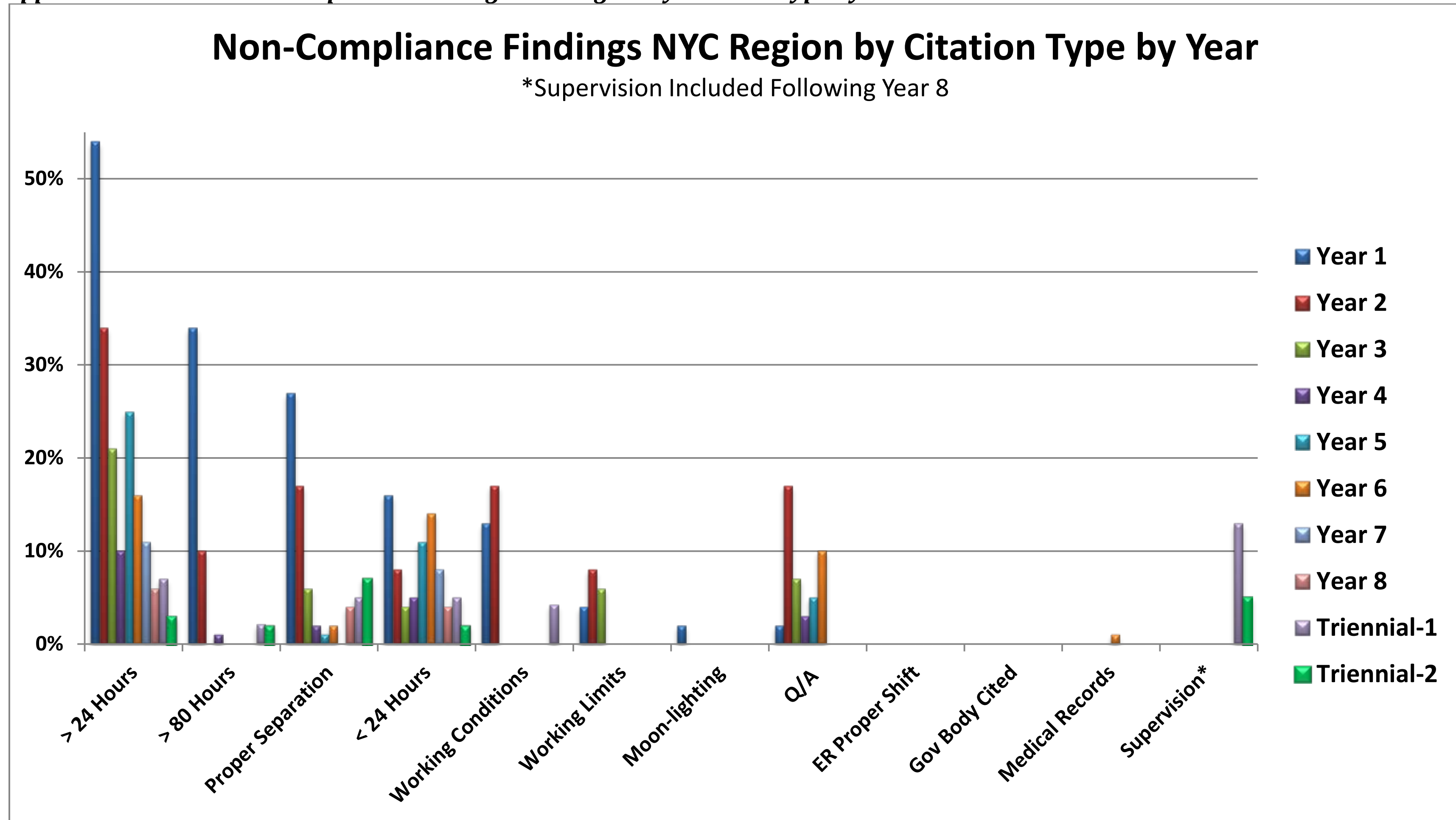
Appendix Exhibit 6: Non-Compliance Findings LHVLI Region by Citation Type by Year



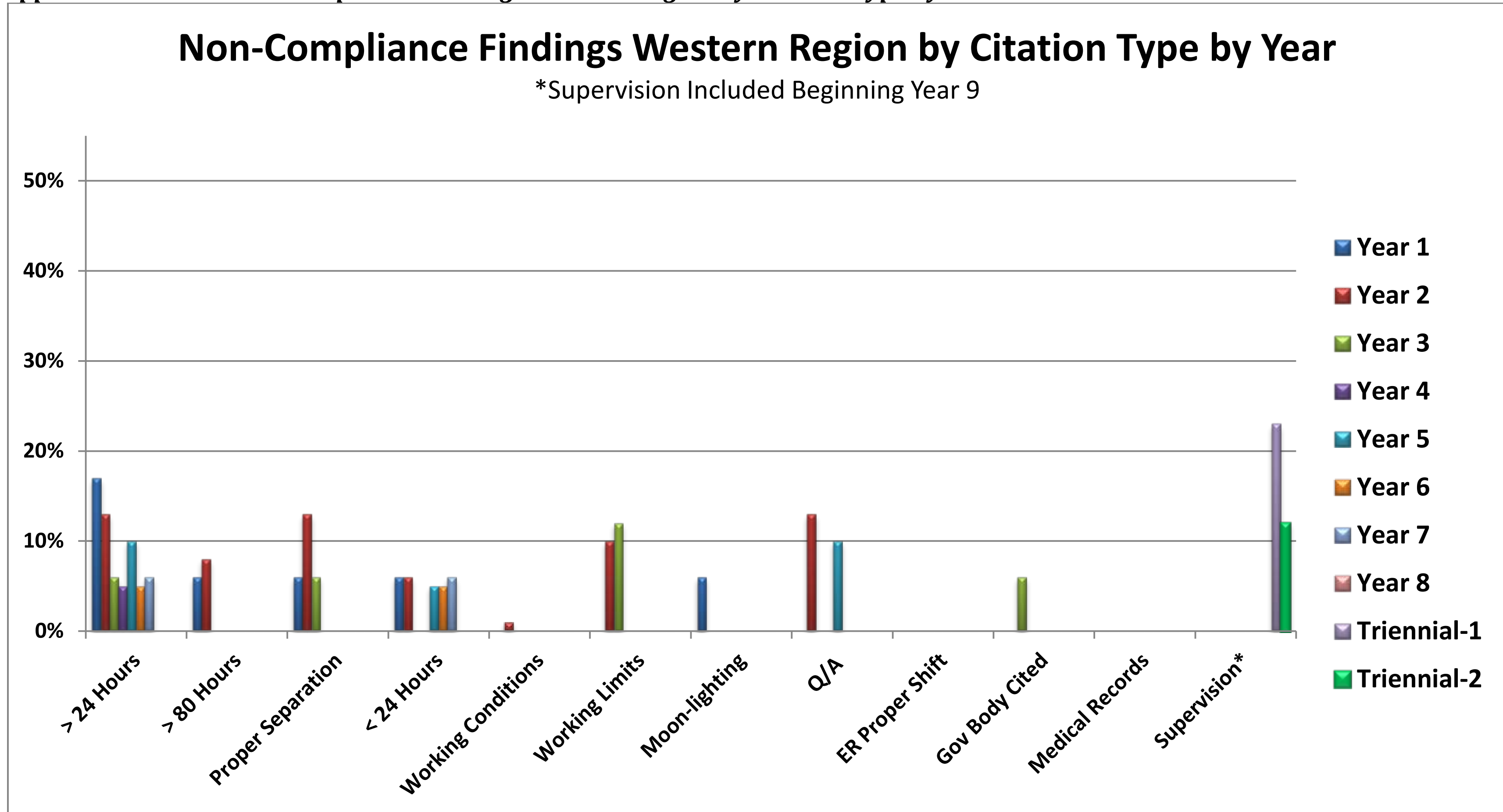
Appendix Exhibit 7: Non-Compliance Findings North East Region by Citation Type by Year



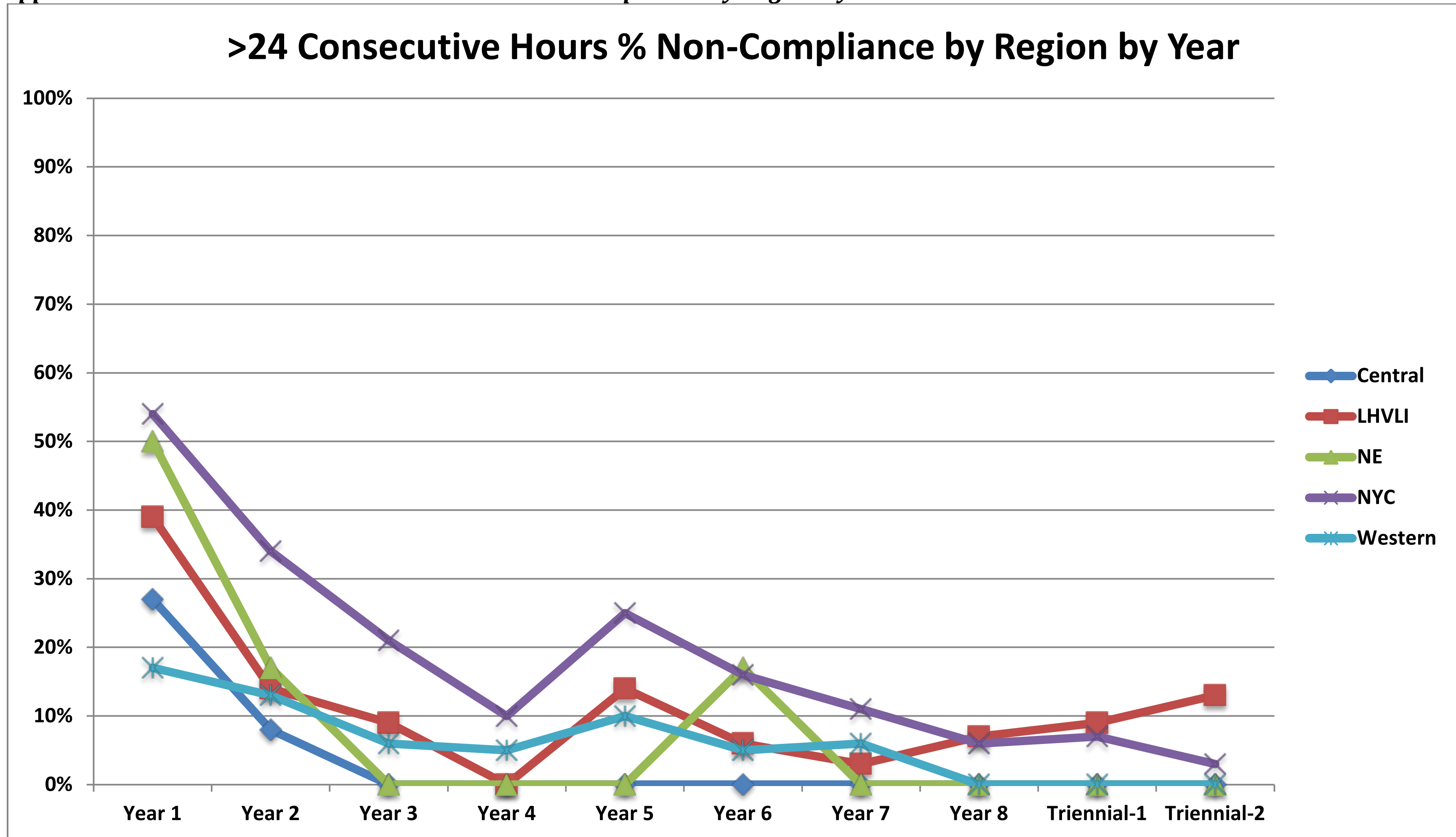
Appendix Exhibit 8: Non-Compliance Findings NYC Region by Citation Type by Year



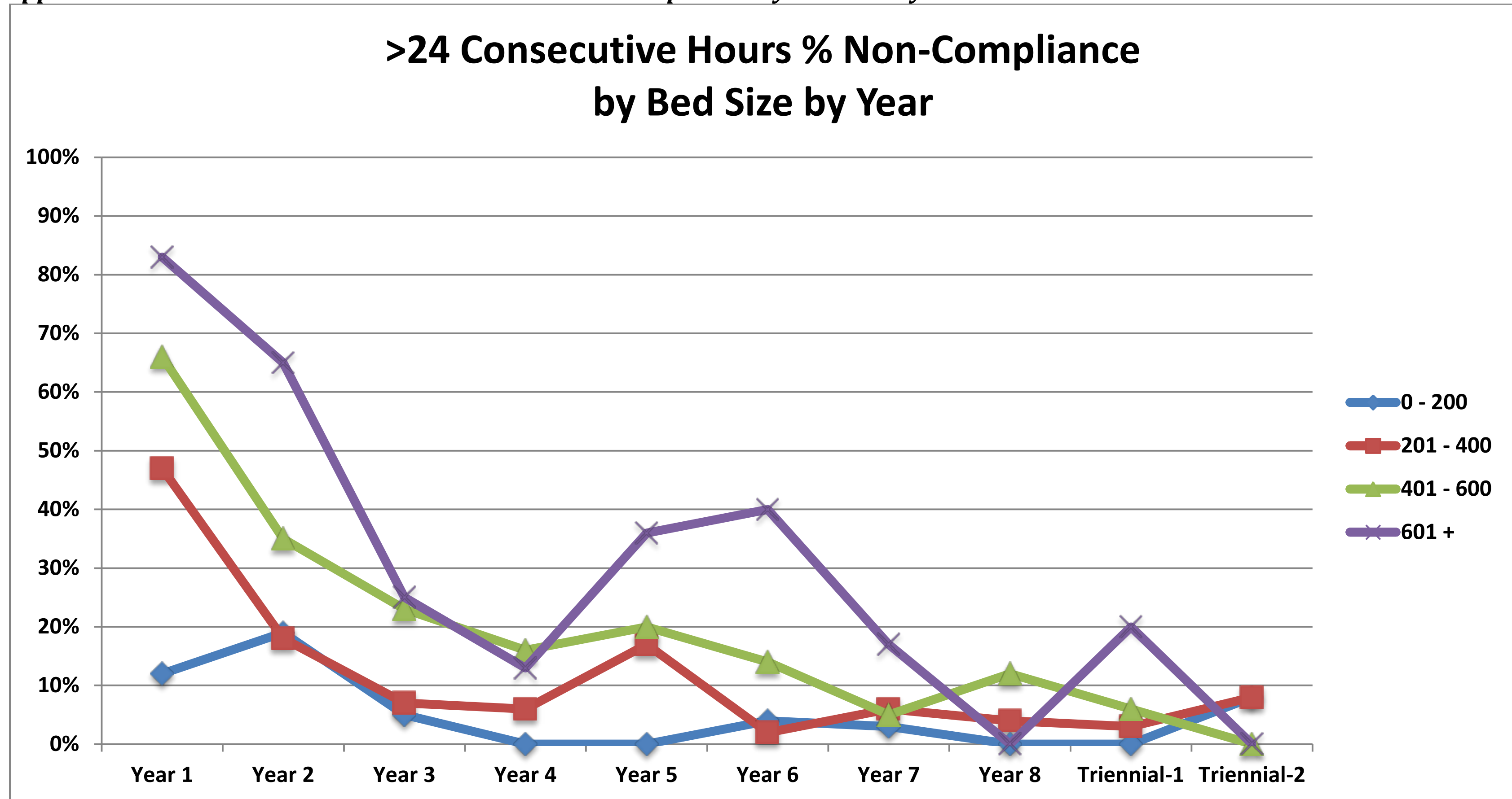
Appendix Exhibit 9: Non-Compliance Findings Western Region by Citation Type by Year



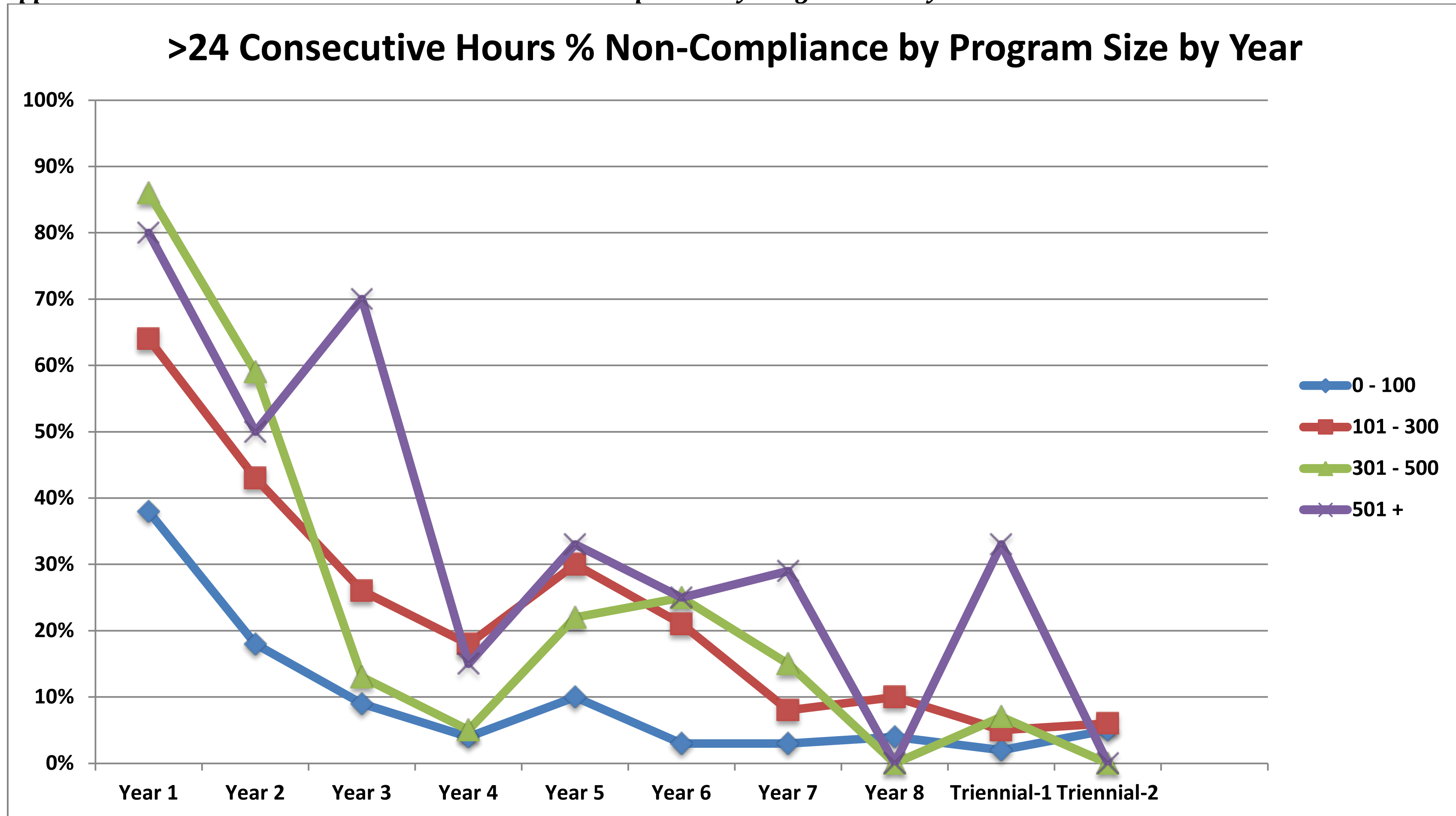
Appendix Exhibit 10: >24 Consecutive Hours % Non-Compliance by Region by Year



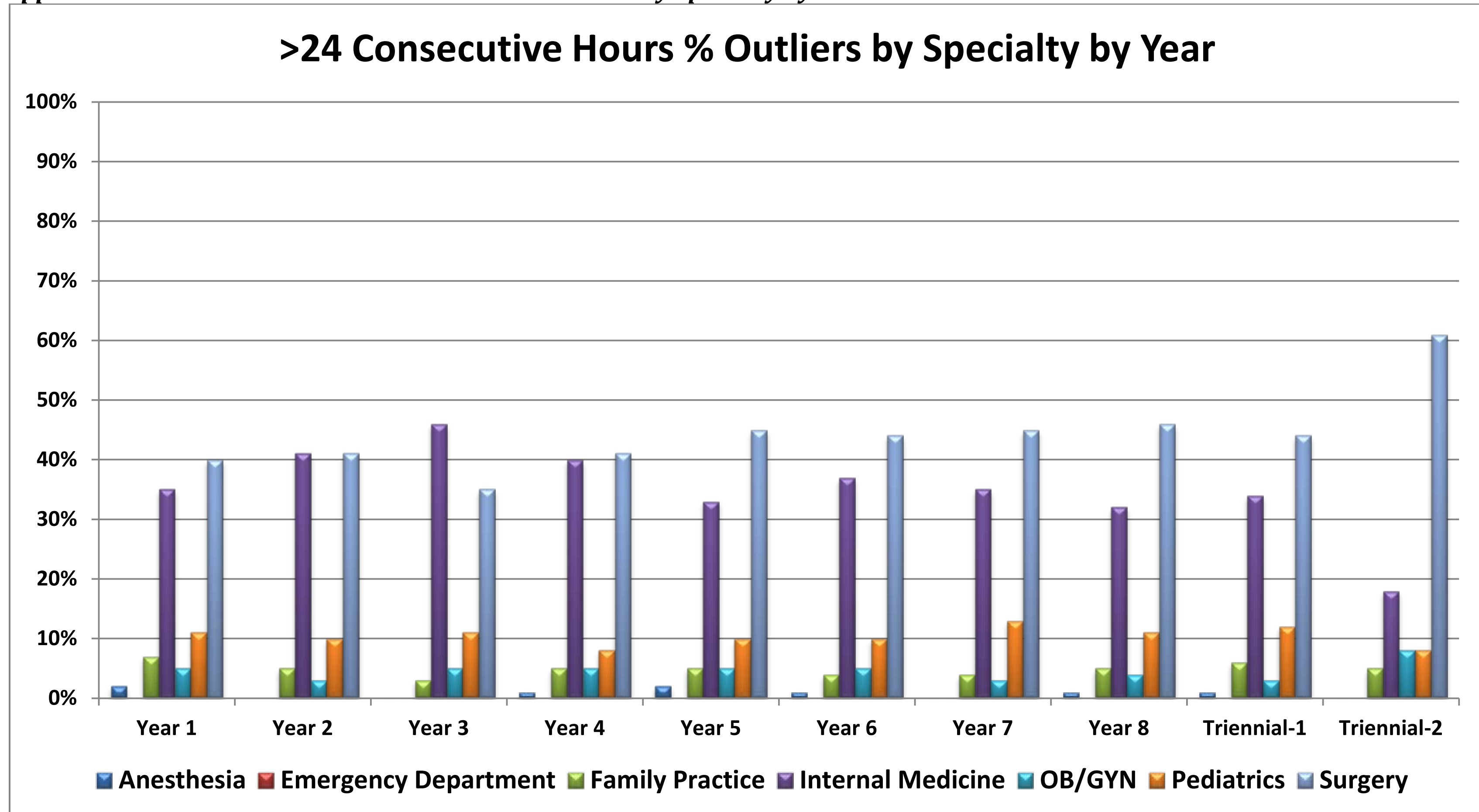
Appendix Exhibit 11: >24 Consecutive Hours % Non-Compliance by Bed Size by Year



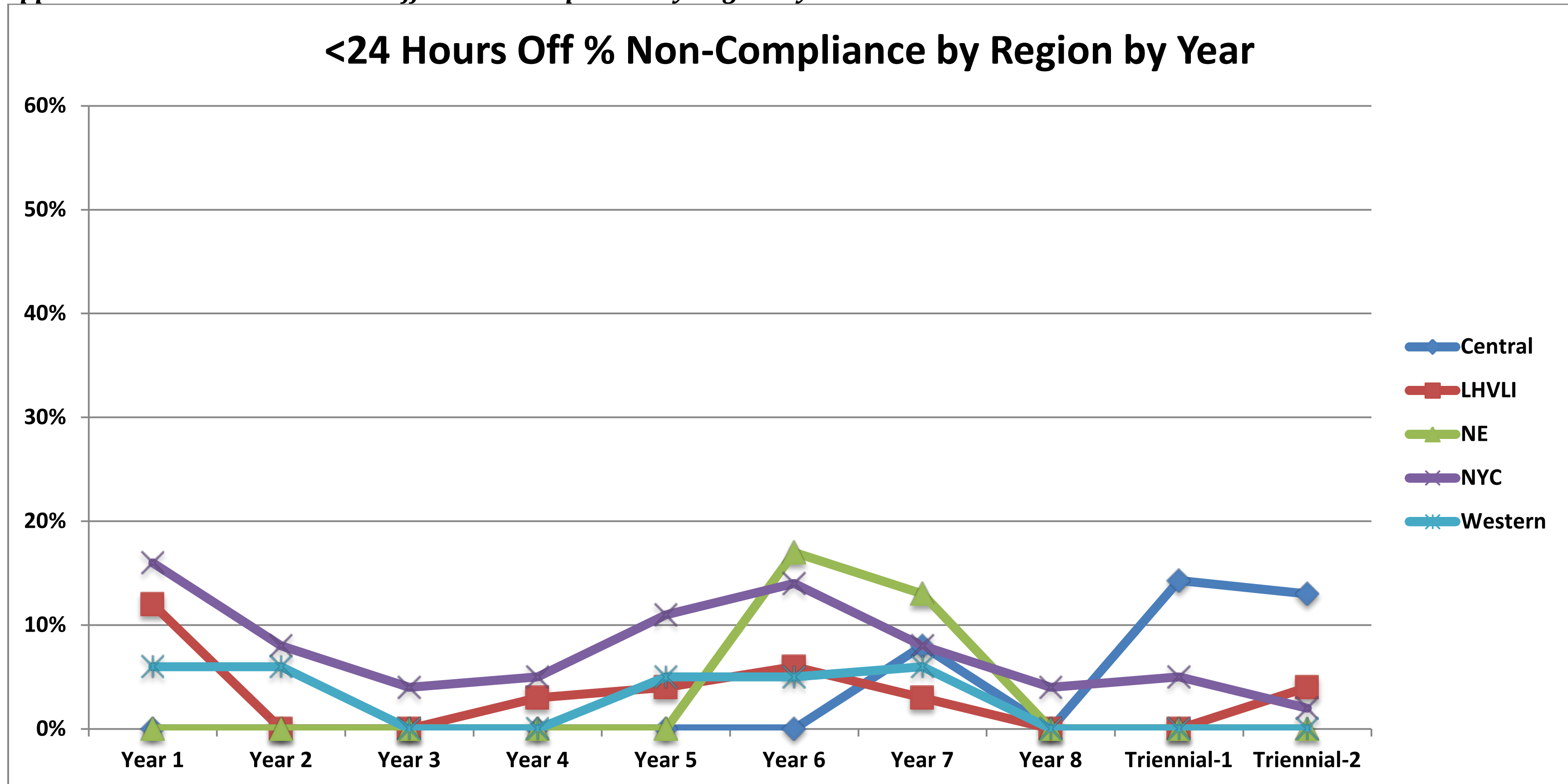
Appendix Exhibit 12: >24 Consecutive Hours % Non-Compliance by Program Size by Year



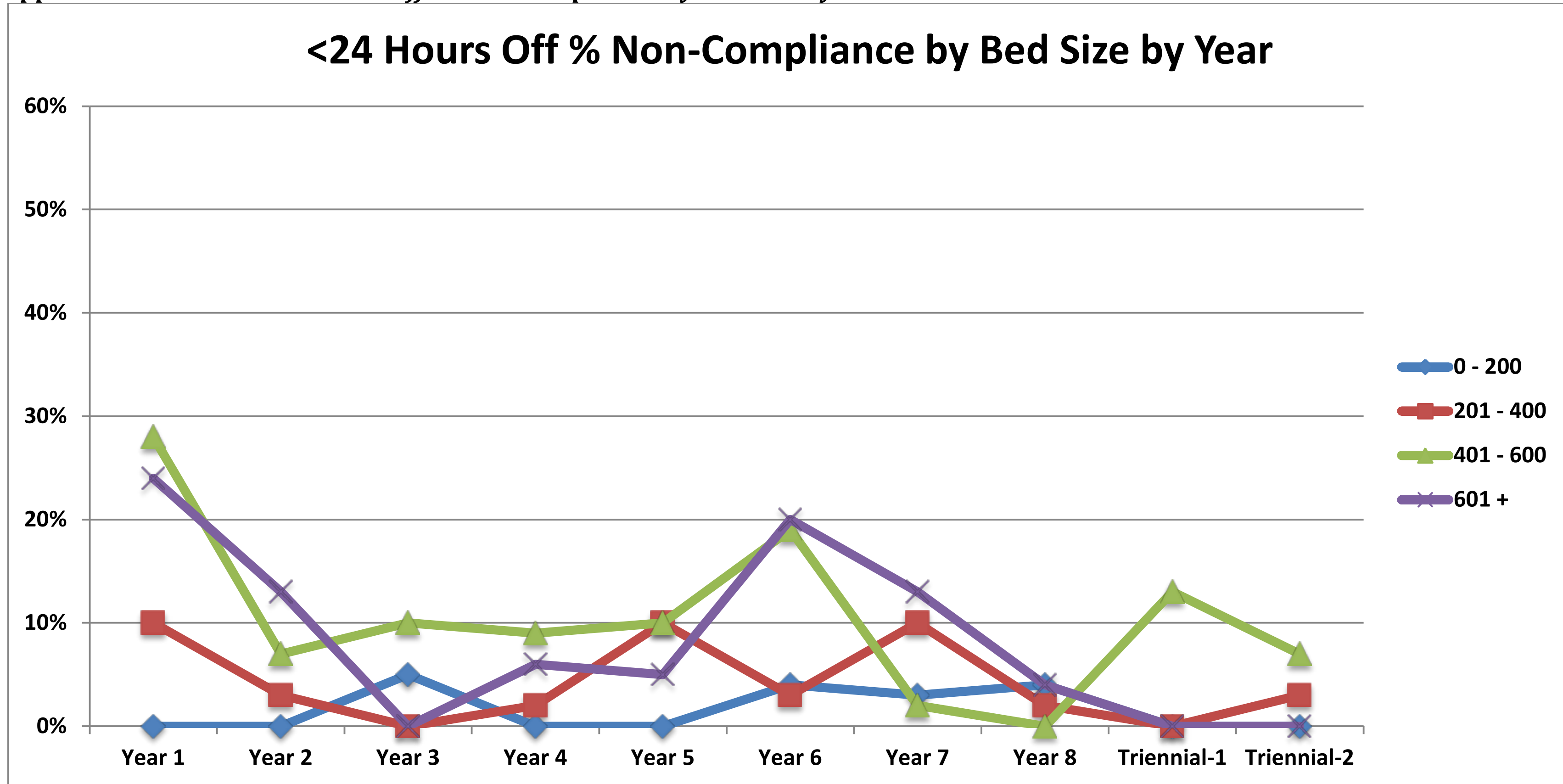
Appendix Exhibit 13: >24 Consecutive Hours % Outliers by Specialty by Year



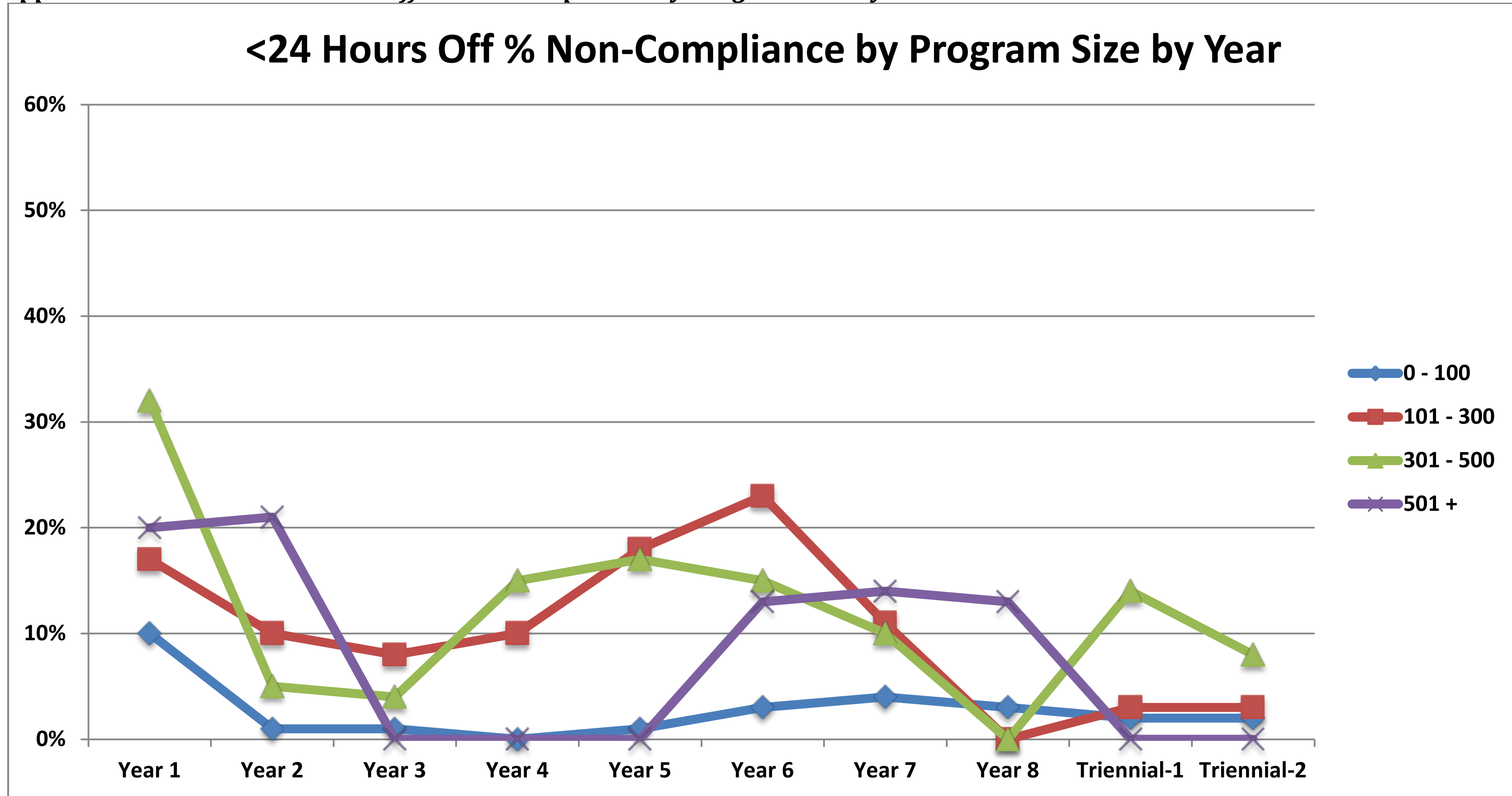
Appendix Exhibit 14: <24 Hours Off % Non-Compliance by Region by Year



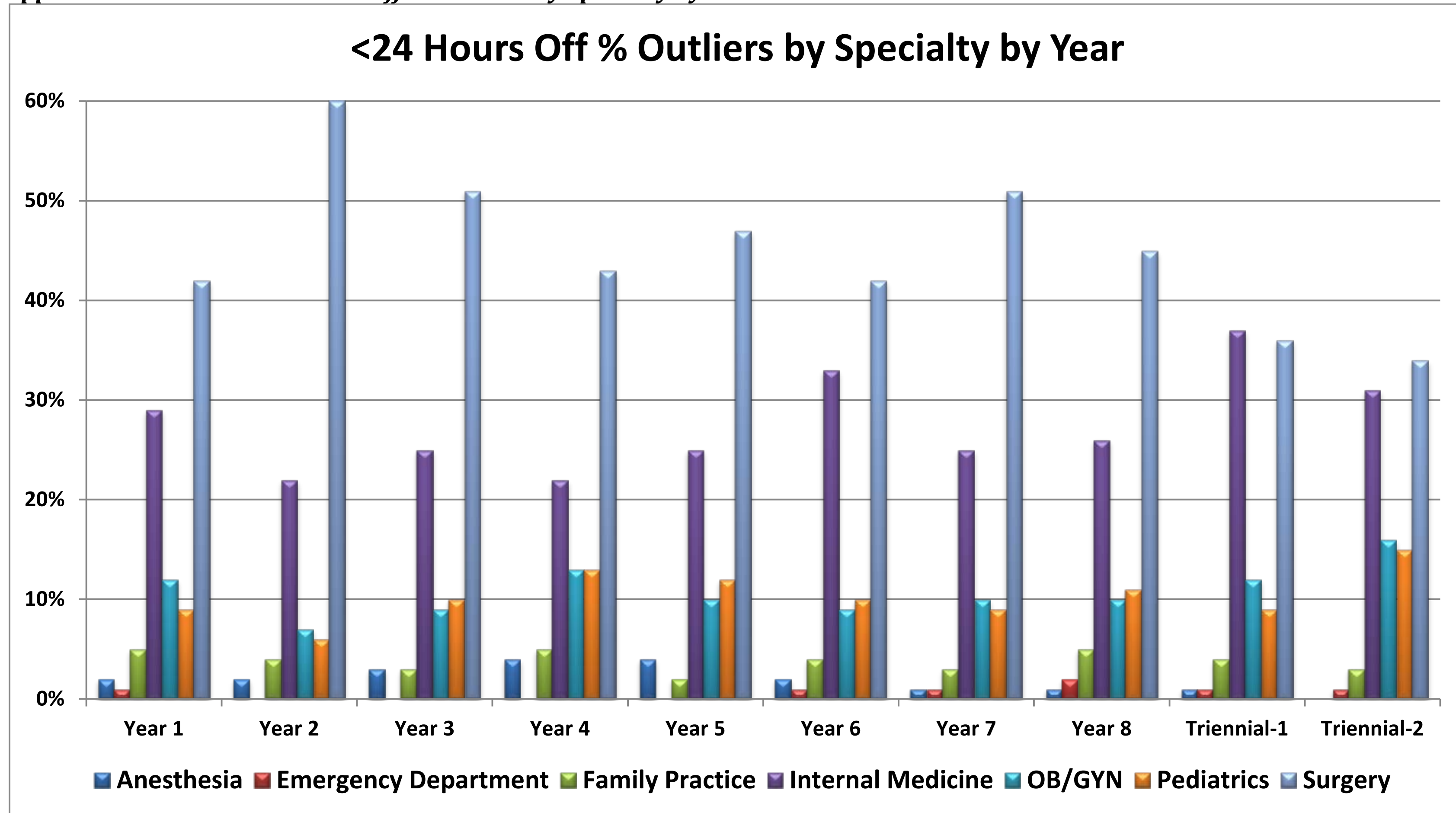
Appendix Exhibit 15: <24 Hours Off % Non-Compliance by Bed Size by Year



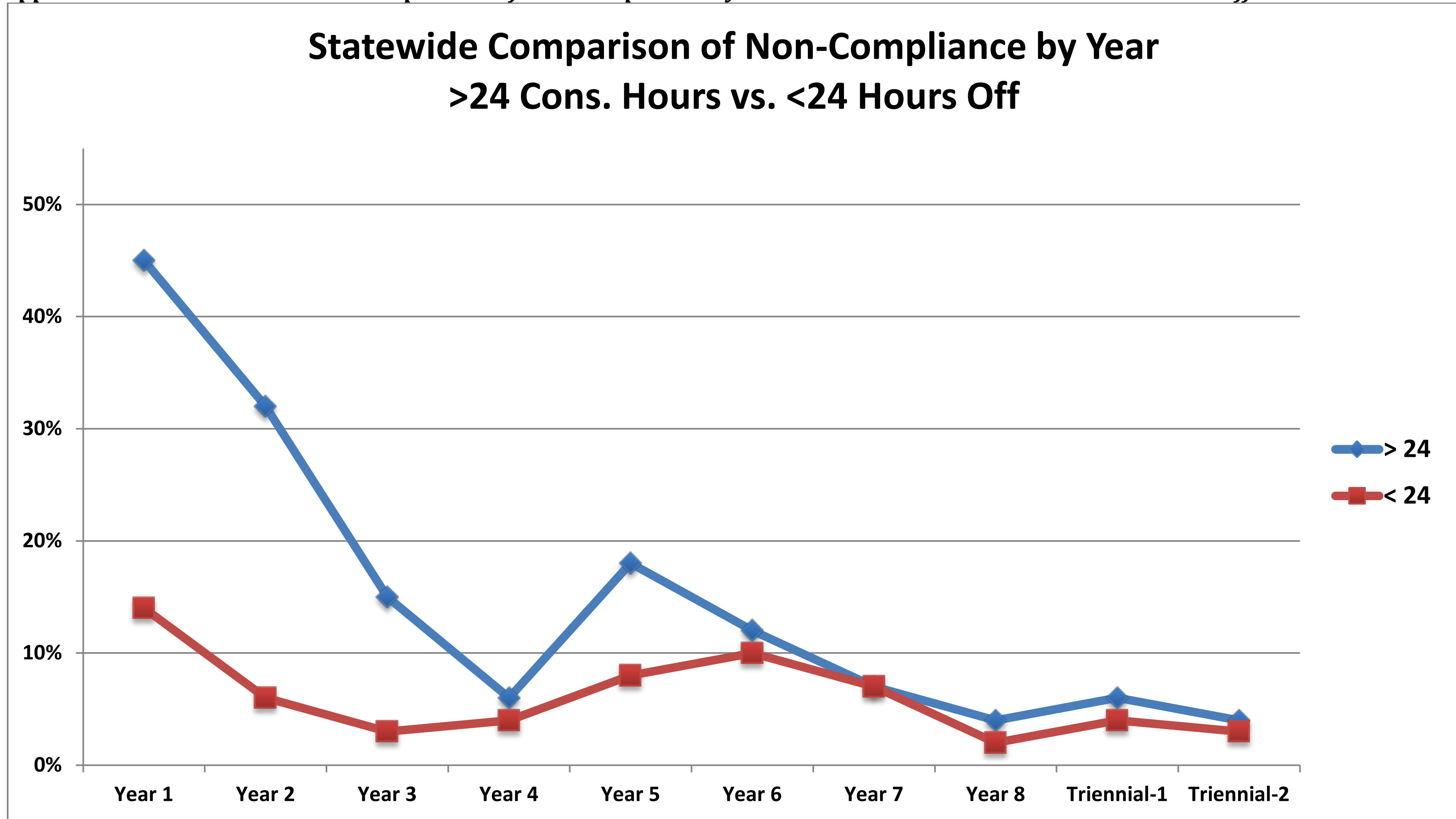
Appendix Exhibit 16: <24 Hours Off % Non-Compliance by Program Size by Year



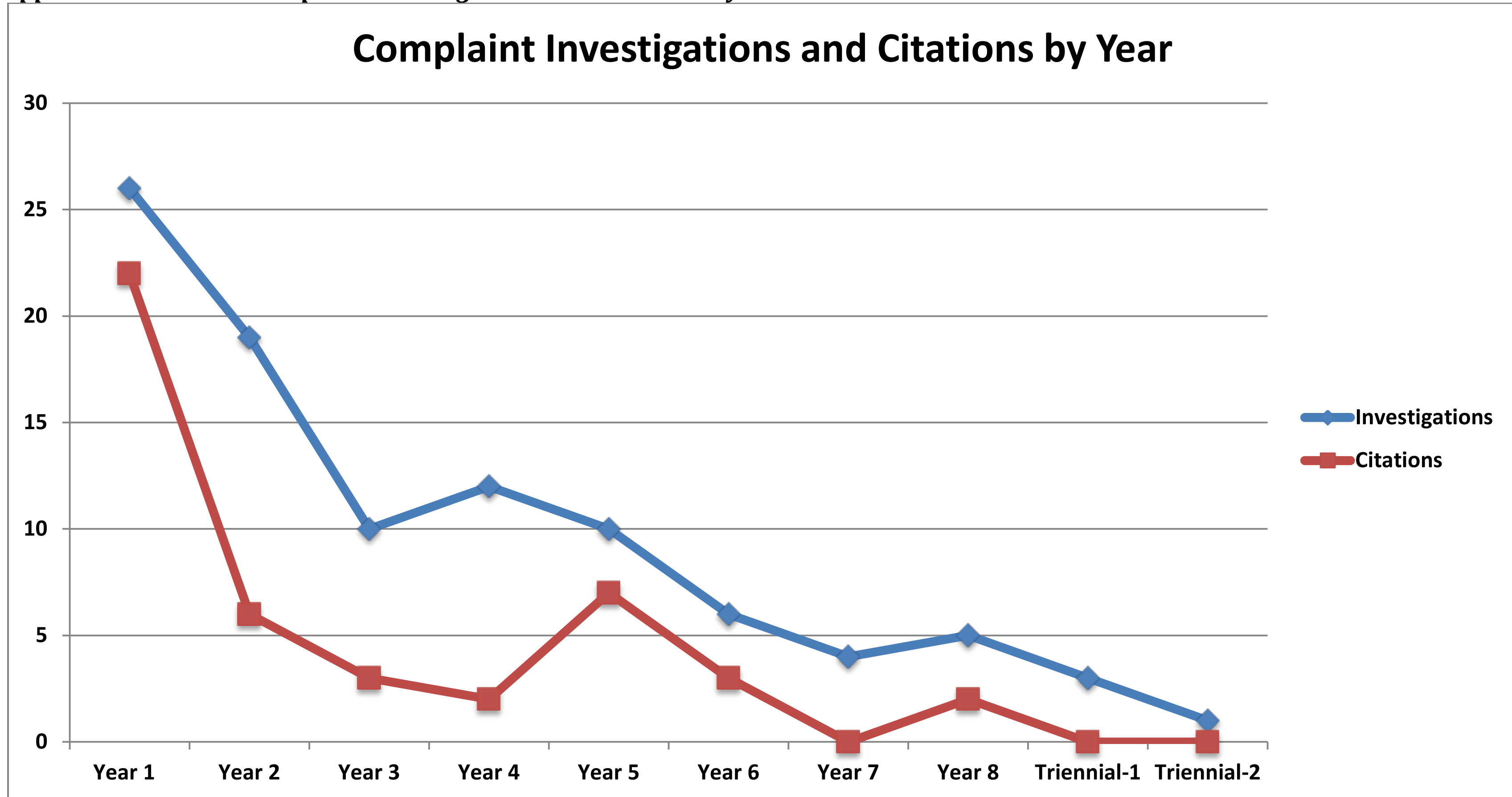
Appendix Exhibit 17: <24 Hours Off % Outliers by Specialty by Year



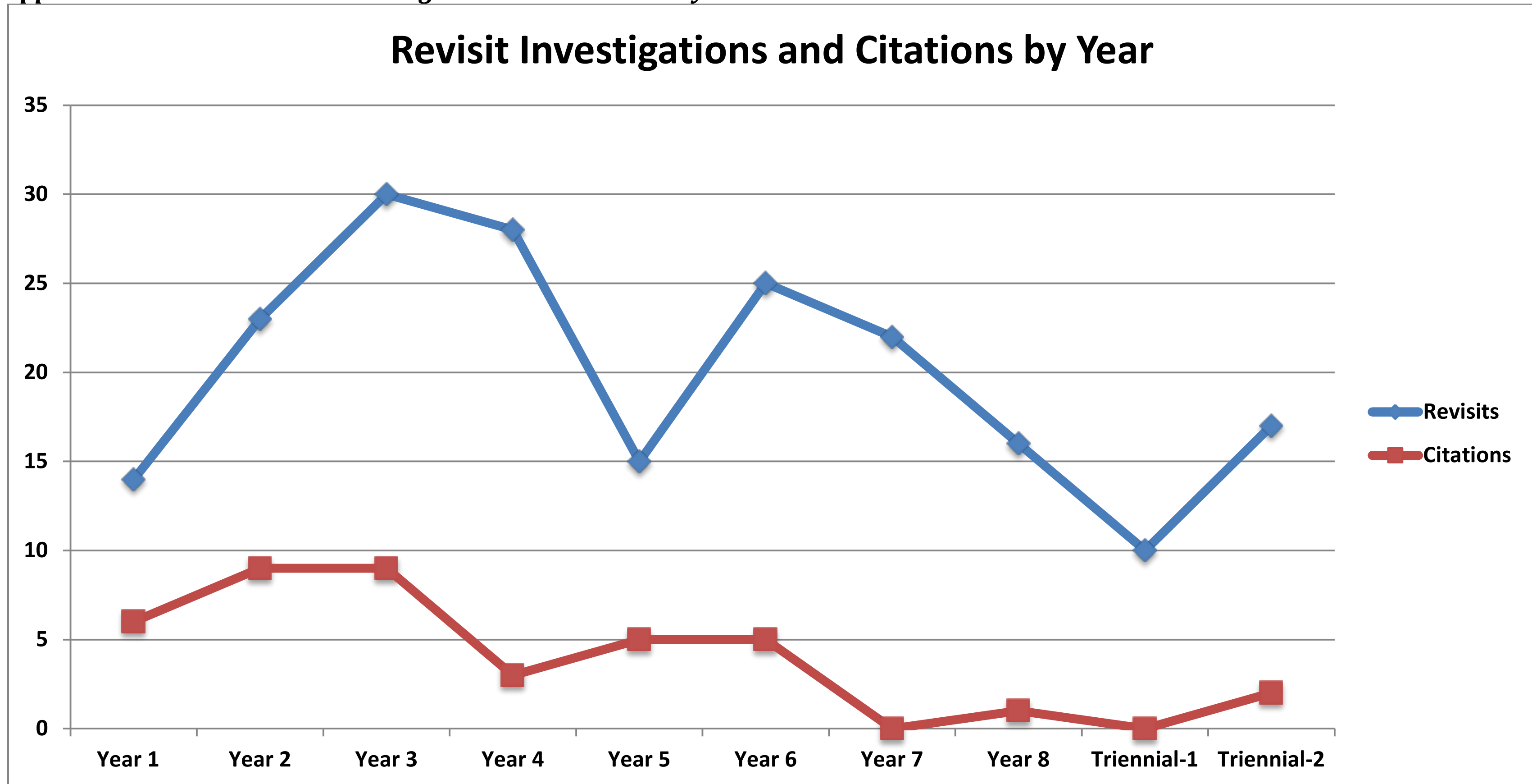
Appendix Exhibit 18: Statewide Comparison of Non-Compliance by Year >24 Consecutive Hours vs. <24 Hours Off



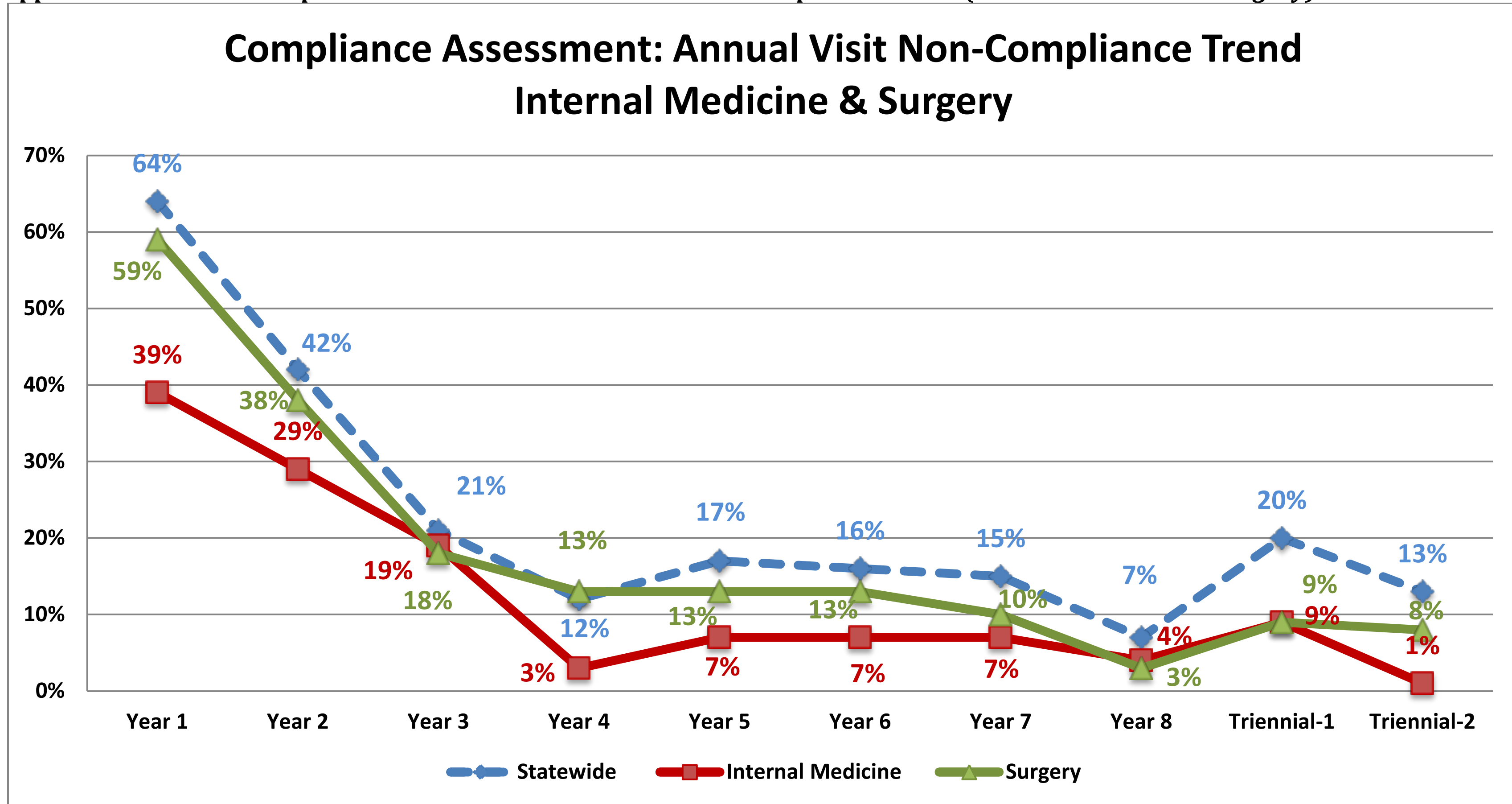
Appendix Exhibit 19: Complaint Investigations and Citations by Year



Appendix Exhibit 20: Revisit Investigations and Citations by Year



Appendix Exhibit 21: Compliance Assessment: Annual Visit Non-Compliance Trend (Internal Medicine & Surgery)



Appendix Exhibit 22: Compliance Assessment: Annual Visit Non-Compliance Trend (All Programs)