

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

Annual Report

October 1, 2014 - September 30, 2015

December 01, 2015



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APPENDICES

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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 (PGTs). In conjunction with the New York State Department of Health (NYSDOH or Department), IPRO has successfully conducted compliance assessments for the past fourteen years.

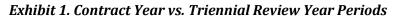
This Annual Report reflects Program operations under the contract period October 1, 2014 to September 30, 2015. The current requirements for Program operations are:

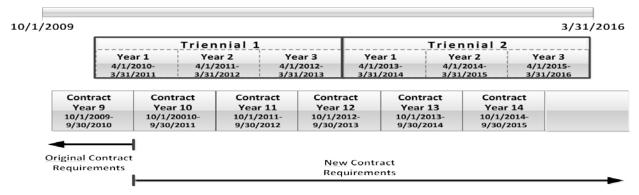
- Onsite compliance reviews to monitor compliance with requirements for work hour limitations and post-graduate supervision provisions to be conducted every third year (or approximately 30 onsite compliance reviews each year).
- Written assessments using a standardized assessment document for facilities 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 (an average of 10-15 per year).
- 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 Department review.
- Monitoring corrective action plans.
- Support of NYSDOH 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 Department for approval, credibility of findings and provider feedback.



1.1. Triennial Review Period vs. Contract Year

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





This difference in triennial review period and the contract year requires recognition of the overlap between the two twelve-month periods. The full contract year for this report (Contract Year-14) falls within the second Triennial Review period.

Under contract years 1-8, 100% of facilities were reviewed each contract year and 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 prior reports included that percentage as the total annual non-compliance rate since it represented a percentage of all facilities. Under the requirements that began on 04/01/10 during Contract Year-9, facilities are being reviewed only once every three years (triennial) and the facilities to be reviewed each year are selected using a variety of factors that do not permit extrapolation of the findings to the universe of all facilities. Mergers, closing facilities, and opening, expanding, or closing of residency programs also contribute to ongoing fluctuation of total facility and/or program counts. 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 annual schedule resulted in findings of non-compliance, this percentage cannot be reported as representative of the entire universe of facilities. It can only be presented as 10% of the facilities reviewed that contract year, with no attribution of that finding to the universe.

For this reason, the findings in this annual report are presented with the stipulation that the data applies only to the facilities reviewed during this contract year timeframe. After all facilities are reviewed over the course of three full years, the cumulative results for all facilities will be reported. In addition, the comparison charts by year from the beginning of the program cannot be updated until the point at which review of the universe of facilities has been completed. Therefore, no comparison charts are included in this report.



1.2. Deliverables

For this Annual Report, the Program requirements have been grouped by type of "deliverable" and the report information is presented addressing each of those deliverables. The deliverable groups and the associated Program requirements are:

- Program Operations Deliverables: Reviews and Investigations
 - Onsite compliance reviews to monitor compliance with requirements for work hour limitations and post-graduate trainee 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.
 - ✓ Onsite complaint investigation and revisits (an average of 10-15 per year).
 - ✓ Monitoring corrective action plans.
 - Ongoing quality review monitoring, including timeliness of conducting reviews, timeliness of submitting surveillance findings to the Department for approval, credibility of findings and provider feedback.
- Program Operations Deliverables: Facility Training and NYSDOH Support
 - ✓ Facility training initiatives.
 - Support of NYSDOH enforcement activities (summary of findings and testimony/expert witness for hearings).
- Program Operations Deliverables: Forms, Protocols and Database Development
 - Ongoing maintenance of a standardized written compliance assessment document for review of facilities not subject to an onsite visit.
 - Ongoing maintenance of onsite survey protocols for reviewing compliance with work hour and supervision requirements.
 - Ongoing maintenance of logs, statewide and regional database and tracking system for Program operations.
- Program Operations Deliverables: Analysis and Reporting
 - Compilation and analysis of findings.
 - Preparation of findings for Department review.
 - Preparation of management reports, including statewide/regional findings, hospital specific reports and quarterly and annual reports.



2.0 COMPLIANCE REVIEWS AND ASSESSMENTS

A total of 117 compliance assessments were conducted in the fourteenth year of the contract from October 1, 2014 to September 30, 2015, specifically:

- Thirty triennial onsite compliance assessment visits,
- Five onsite revisit assessments,
- No onsite complaint investigations, and
- Eighty-two written (off-site) compliance assessments.

This total reflects the program changes made based on the contract awarded in April 2010, which included (a) a change from annual onsite visits to triennial onsite visits for teaching hospitals with more than ten post-graduate trainees, (b) focusing on the working hours and conditions of PGT levels 1-3, and (c) overall assessment of PGT access to and the quality of supervision provided by supervising physicians. Facilities with ten or less post-graduate trainees and those facilities not scheduled for an onsite triennial visit are surveyed through a written compliance assessment.

In total, 1,833 PGTs in the State were interviewed during Contract Year-14 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 NYSDOH. 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.

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. Triennial Onsite Compliance Assessments

2.1.1. Implementation of Visits

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 2, Distribution of Facilities by Region. The distribution of facilities by bed size and by program size is shown in Exhibit 3, Distribution of Facilities by Bed Size and Exhibit 4, Distribution of Facilities by Program (# of PGTs) Size respectively. As indicated previously, differences in these charts from previous years are due to mergers, closings, new and/or expanded programs.



Region	Counties/Boroughs with Teaching Hospitals	# of Facilities
Central	Broome, Jefferson, Oneida, Onondaga	9
Lower Hudson Valley & Long Island (LHVLI)	Nassau, Rockland, Suffolk, Ulster, Westchester, Orange	29
Northeast (NE)	Albany, Clinton, Otsego, Schenectady	6
New York City (NYC)	Bronx, Kings, New York, Richmond, Queens	50
Western	Cattaraugus, Erie, Monroe, Niagara, Steuben, Chemung	15
	109	

Exhibit 3. Distribution of Facilities by Bed Size

Bed Size Categories	# of Facilities
0-200	18
201-400	48
401-600	28
600+	15
TOTAL	109

Program Size Categories	# of Facilities
0-80	56
81-200	20
201+	33
TOTAL	109

Under the triennial review requirements, onsite surveys are planned throughout each year of the triennial cycle by region, with a mix of small (\leq 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 are made as needed to allow for facility and/or program closures, expansions, or mergers/acquisitions. Of note, visits were suspended from the end of October through early December due to preparedness for the Ebola crisis.

The distribution of the 30 triennial assessments completed relative to the universe of 109 total facilities is shown in Exhibit 5, Thirty Visits as % of Total Facilities by Region; Exhibit 6, Thirty Visits as % of Total Facilities by Bed Size and Exhibit 7, Thirty Visits as % of Total Facilities by Program Size.



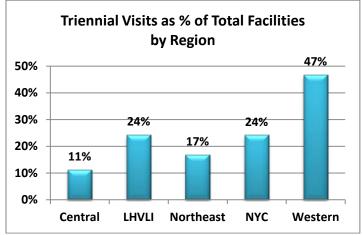
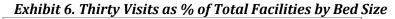
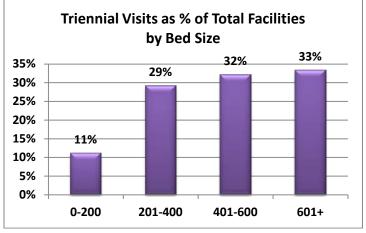


Exhibit 5. Thirty Visits as % of Total Facilities by Region







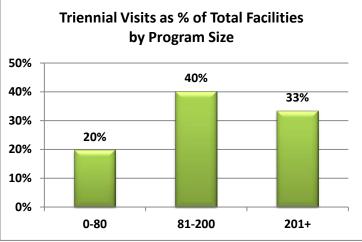




Exhibit 8, Triennial Compliance Visits Completed by Month, shows the distribution of the 30 triennial reviews that were completed by month during Contract Year-14 between October 2014 and September 2015. As indicated previously, while visits were suspended from late October through early December, the visits in November shown in Exhibit 8 are those completed from October.

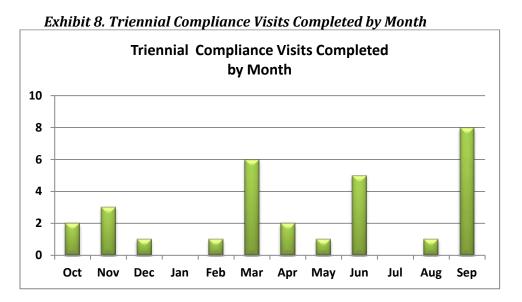


Exhibit 9, Triennial Compliance Visits Completed by Quarter by Region, shows the distribution of the 30 triennial reviews, by region across the state.

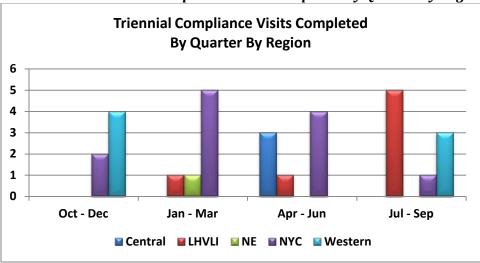


Exhibit 9. Triennial Compliance Visits Completed by Quarter by Region



2.1.2. Distribution of Findings

Thirty triennial compliance visits were conducted under the terms of the contract, where each teaching facility with more than ten PGTs receives an onsite compliance visit once in three years. Of these 30 triennial visits, three evidenced some level of non-compliance at the time of the onsite review. 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.

As previously noted, the results of the 30 triennial compliance assessment visits conducted during Contract Year-14 can only be attributed to the facilities that were assessed, not to the universe of all facilities. Two facilities cited for non-compliance in Contract Year-14 evidenced non-compliance in only one program area, and one facility was cited for non-compliance in two programs.

Exhibit 10, Triennial Compliance Assessment Visit Results, shows the percentage distribution of the 30 triennial reviews, by compliance and non-compliance.







Exhibit 11, Triennial Compliance Assessment Visits-Results by Region, shows the distribution of the 30 triennial reviews, by compliance and non-compliance on a regional basis.

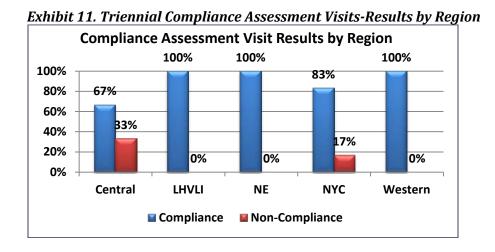


Exhibit 12, Triennial Compliance Visits Conducted and Citations by Month, illustrates the distribution of the 30 triennial visits compared to the findings of non-compliance for visits completed each month. It does not appear that survey outcome was influenced by survey scheduling, which is consistent with previous years' findings. 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 year.

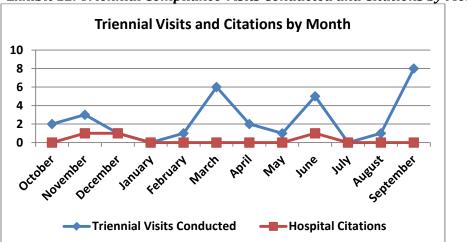


Exhibit 12. Triennial Compliance Visits Conducted and Citations by Month



Exhibit 13, Triennial Compliance Visits-Non-Compliance Findings by Bed Size, presents a detailed assessment of compliance by bed size for the 30 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 (i.e., 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 subspecialties were included under the primary program category.

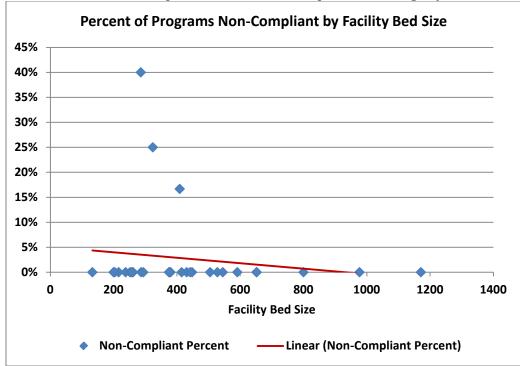


Exhibit 13. Triennial Compliance Visits-Non-Compliance Findings by Bed Size

None of the triennial visits conducted evidenced non-compliance in every teaching program reviewed at that site. Since these reviews are a subset of the universe of facilities, no conclusion regarding the potential relationship can be made until the full three-year review cycle is completed.



2.2. Summary of Findings - All Compliance Assessments

2.2.1. Summary of Findings-Onsite Compliance Reviews A total of 35 visit types (30 triennials and 5 revisits) at 30 onsite visits were conducted during Contract Year-14. Findings include the following:

- Three hospitals were cited for non-compliance:
 - ✓ Three facilities were cited for the triennial visit;
 - In two of the facilities cited, one program area within the facility evidenced non-compliance with one review criteria;
 - In one of the facilities cited, one program area within the facility evidenced non-compliance with one review criteria and one program evidenced noncompliance with two review criteria;
 - ✓ Of the three facilities cited for non-compliance, four (4) total programs were cited with a total of five (5) individual citations.

The statewide findings of non-compliance for the 35 total visit types at 30 facility onsite visits 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. No facility was cited for working hours in excess of 80 hours each week.
- 24 Consecutive Hours. Regulations limit scheduled assignments to no more than 24 consecutive hours. *Two facilities were cited for residents working more than 24 consecutive hours.*
- 24 Hours Off Period. Scheduling must include one full 24-hour off period each week.
 Two facilities were cited for residents not having one full 24-hour off period each week.
- Proper Separation. Assigned work periods must be separated by not less than eight non-working hours. One facility was cited for working assignments not separated by required non-working time.
- Working Conditions. This category includes consideration for sleep/rest accommodations, the availability of ancillary and support services, and the access to and availability of supervising physicians to promote quality supervision. No facility was cited for failing to meet expected working conditions for residents.
- Supervision. Under the terms of the new contract, there is enhanced monitoring of supervision. The intent is to review for access and availability 24/7 by the attending physician to provide supervision of all trainees with ongoing evidence in the medical record. Trainees in their final year or who have completed at least three



years of training may provide supervision if it can be demonstrated that the attending is immediately available by phone and readily available in person. For surgical programs, the regulations require 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. No facility was cited for improper medical record documentation of post-graduate trainee supervision.

- Working Limitations. 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, operating room logs or 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 Contract Year-14 were cited for deficiencies in their QA/QI performance. It should be noted that QA/QI would automatically be cited in Contract Year-14 for any facility that had a repeat deficiency from Contract Year-13 or in the case of a Contract Year-14 revisit, a repeat of findings in Contract Year-14.
- 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 Contract Year-14, 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 in Contract Year-14.
- 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 Contract Year-14.
- Medical Records. Medical record documentation and authentication regulations require that all medical record entries be signed, dated, and timed. No facilities visited in Contract Year-14 were cited for deficiencies with medical record entry requirements.



Exhibit 14, Non-Compliance Findings Statewide and by Region – All Visits, illustrates the findings of non-compliance for all onsite visits conducted.

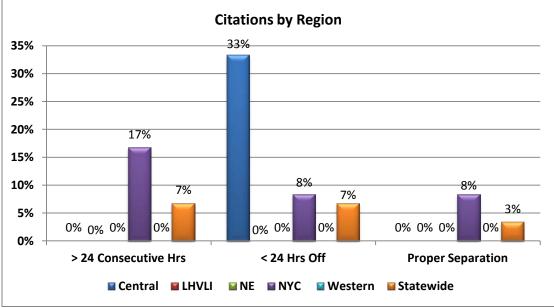


Exhibit 14. Non-Compliance Findings Statewide and by Region-All Visits

2.2.2. > 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.

For all onsite surveys conducted in Contract Year-14, non-compliance was evidenced in two facilities.

Exhibit 15, Statewide Distribution of Outliers by Specialty: >24 Consecutive Hours illustrates, of the 35 total visits, the percentage by specialty of the PGTs identified, but not necessarily cited, as having worked more than 24 consecutive hours. Surgery and OBGYN residents were the most frequently identified.



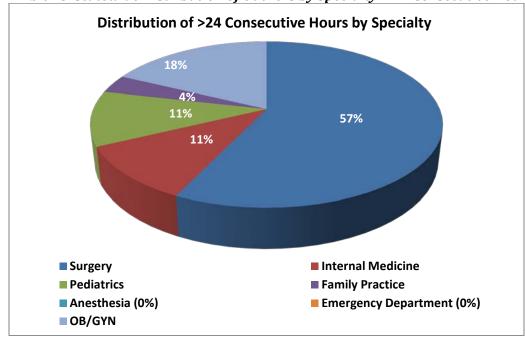


Exhibit 15. Statewide Distribution of Outliers by Specialty: >24 Consecutive Hours

2.2.3. <24-Hour Off Period

New York State regulations require that scheduling must include one full 24-hour off period each week free from patient care assignments or responsibilities. 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 providing a 24-hour off period each week is ensuring that there are 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, for example, back-up call every day for one month, the trainee would not have the required 24-hour off period per week.

For all onsite surveys conducted in Contract Year-14, non-compliance was evidenced in two facilities.

Exhibit 16, Statewide Distribution of Outliers by Specialty, <24 Hours Off, illustrates for the 35 total visits conducted, the percentage by specialty of the PGTs identified, but not necessarily cited, as not having one full 24-hour off period each week. Surgery and internal medicine residents were the most frequently identified, which may be attributed, in part, to the fact that each category includes numerous subspecialties and accounted for more than half of the programs reviewed during this timeframe.



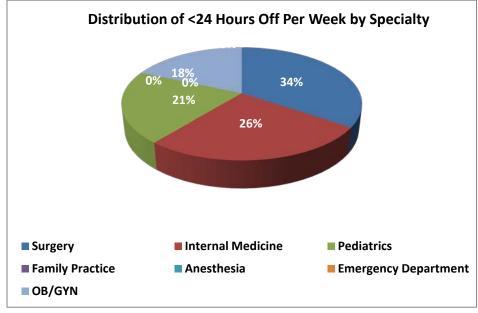


Exhibit 16. Statewide Distribution of Outliers by Specialty, <24 Hours Off

2.2.4. Facility Revisits and Monitoring of Corrective Action Plans Results Corrective Action Plans and implementation are monitored through revisits, which are conducted as a separate visit or at the time of the next onsite survey. For revisits conducted in Contract Year-14:

- Facility plans of correction (POCs) and implementation for previously identified non-compliance were monitored through five facility onsite revisits.
- 100% of revisits evidenced substantial compliance with the POC.

2.2.5. Onsite Complaint Investigation Results

There were no onsite complaint investigations conducted in Contract Year 14.

2.2.6. Written (Off-Site) Assessment Results

No concerns were identified for the 82 off-site compliance assessments.

2.2.7. Facility Program Changes / Strengths

IPRO continues to track changes facilities have made in response to the duty hours based on discussions with program directors, program coordinators and/or other program representatives. While the categories of changes/program strengths remain fairly consistent year to year, specific activity within each category is dynamic as programs continue to evaluate and implement processes and systems to best meet their needs.



The changes are summarized below:

- Schedules
 - ✓ Continued use of night float/shift systems.
 - Changed time of morning and/or afternoon sign-outs to increase attendance while remaining compliant with work-hour regulations.
 - Changed time and/or allocation of last admit to allow residents to complete work and leave on time.
 - ✓ Use of a one-week clinic rotation (i.e., "4 + 1") which provides adequate and uninterrupted floor coverage, and improved clinic time and education.
- Staffing
 - Use of Hospitalists, Nurse Practitioners and Physician Assistants for coverage.
 - ✓ Increased number of residents or other practitioners used in call schedule.
 - ✓ Use of in-house moonlighting to cover call.
 - ✓ Re-allocated resources to cover busier services/times.
- Education/Procedural
 - ✓ Protected education time for residents.
 - Changed clinic and/or conference times to allow attendance by night floats and/or post-call residents.
 - ✓ Conferences and presentations available on-line.
- Software
 - ✓ Software for duty hour monitoring.
 - ✓ Software for handoffs.
- Other
 - ✓ Ease of access to all required survey information.
 - ✓ Well-written policies that clearly define New York State regulations.



3.0 ONGOING QUALITY REVIEW MONITORING

As part of the quality monitoring system, IPRO monitors all aspects of the contract requirements and takes necessary action as needed, such as development and distribution of brochures and tips sheets, in response to survey findings/trends. Monitoring includes but is not limited to:

- survey processes, such as unannounced visits, staggered survey schedule, and site review protocols,
- tracking and trending of residency program changes/ strengths,
- survey findings for issues/trends,
- feedback and other communications with facilities or other interested parties, and
- internal program performance including effectiveness of processes and timeliness of all survey activities.



4.0 FACILITY TRAINING AND DOH SUPPORT

IPRO continues to provide training and updates as requested by facilities and other collaborators/special interest groups. During Contract Year-14, IPRO:

- provided various informal discussions at onsite surveys, as well as responses to telephone calls and emails focused on the general work hour regulations.
- visited two new residency programs at onsite surveys, providing information and guidance while onsite;
- continued to distribute Resident Work Hour Brochures upon request and to residents during onsite survey interviews.



5.0 FORMS, PROTOCOLS AND DATABASE MANAGEMENT

In cooperation with the Department, IPRO developed and implemented a standardized written compliance assessment tool in Contract Year-9. This tool continues to be used in the assessment of all facilities not subject to an onsite compliance visit. The tool is included in Appendix A.

Onsite survey protocols previously developed and implemented continue to provide a standardized and seamless approach to implementation of contract requirements as well as continuity of processes for facilities and staff. IPRO continues to use and modify as needed the existing logs, databases and tracking system to accommodate the program requirements.



6.0 Analys is and Reporting

In consultation with the Department, IPRO developed reports to reflect the contract requirements. Quarterly and annual reports are prepared and provided to the Department for their review. Following Department review, the reports are modified, if necessary, and finalized for submission to the Department. During Contract Year-14 the following reports have been submitted:

- Post Graduate Trainee Working Hours & Conditions, Quarterly Report, October 1, 2014 - December 31, 2014
- Post Graduate Trainee Working Hours & Conditions, Quarterly Report, January 1, 2015 - March 31, 2015
- Post Graduate Trainee Working Hours & Conditions, Quarterly Report, April 1, 2015 – June 30, 2015
- Post Graduate Trainee Working Hours & Conditions, Quarterly Report, July 1, 2015 - September 30, 2015.



APPENDIX A. ANNUAL OFF-SITE COMPLIANCE ASSESSMENT TOOL

The off-site assessment form that follows was developed under the requirements of the new contract for 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.



