NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

April 16, 2014

Dear Chief Administrative Officer:

This letter is to inform you of recent amendments to 10 NYCRR Part 405 concerning general hospitals, which became effective on December 31, 2013. Facilities are required to be compliant with the regulations effective March 31, 2014. These amendments update the minimum standards for administration, radiology/nuclear medicine, pharmacy services, admission and discharge, quality assurance, respiratory, emergency, surgical, and anesthesia services, and include new requirements for pediatric care, including standards for pediatric intensive and emergency care.

The pediatric minimum standards are the recommendation of the Emergency Medical Services for Children Advisory Committee, an advisory committee to the Commissioner of Health on medical and public health issues concerning infants and children and are consistent with national standards from the; American Academy of Pediatrics, Society of Critical Care Medicine, American College of Surgeons, American College of Emergency Physicians, American Pediatric Surgical Association, and Federal EMS for Children Program.

The purpose of these regulations is to improve the care of children. For example, prior to these revisions there were no specific minimum standards for pediatric critical care. These regulations address this and direct hospitals to have the proper personnel and equipment to care for children and to transfer those that they cannot care for to an appropriate facility. The following sections of 10 NYCRR Part 405 are amended:

- 405.3 Administration - This section is updated to reflect more current terminology used for certain health professions, such as social workers and respiratory therapists.

- 405.6 Quality Assurance - This section is updated to assure hospitals admit only those patients for which they have the appropriate staff, resources and equipment, and transfer those patients if they do not have the capability (exception given for disasters).

- 405.7 Patient Rights - This is amended to establish a **"**Parent's Bill of Rights" which advises parents/guardians of their rights under the amendments and requires distribution and posting of the Parent's Bill of Rights.

- 405.9 Admission/Discharge and 405.19 Emergency Services - These sections are amended to require written policies and procedures pertaining to the review and communication of laboratory and diagnostic test/service results ordered for a patient while admitted or receiving emergency services. Prior to discharge, all "critical value" laboratory and diagnostic tests/service results are to be reviewed and communicated to the patient by a physician (MD), physician assistant (PA) or nurse practitioner (NP) familiar with the patient's presenting condition. "Critical value" results are defined as those that suggest a life threatening or otherwise significant condition such that requires immediate medical attention. All laboratory and diagnostic test results are to be forwarded to the patient's primary care provider, if known, after review by an MD, PA or NP.

- 405.7 Patient Rights - In regards to pediatric patients, this section allows one parent/guardian to stay with the patient at all times, to the extent possible given the patient's health and safety.

- 405.15 Radiology - This section is updated to meet current standards of practice, e.g. "linear accelerators" are added, and "MVE units" is deleted. It also requires a policy be developed for imaging studies for newborns and pediatric patients that includes clinical appropriateness, dosage, beam collimation, image quality and shielding.

- 405.12 Surgical Services, 405.13 Anesthesia Services and 405.14 Respiratory Services These sections are amended to reflect current practices, such as deleting reference to antiquated medical terms and adding that equipment must be age and size appropriate.

- 405.17 Pharmaceutical Services – This section is updated to require all patients be weighed using metric system values to assist in preventing medication errors.

- 405.19 Emergency Services – This section is amended to require Pediatric Advanced Life Support (PALS) training when children are being treated.

- 405.20 Outpatient Services - This section is amended to clarify ambulatory surgery services must have the appropriate equipment necessary to meet the needs of all patients and adds the parents, legal guardian or health care agent.

- 405.22 Critical Care and Special Services - This section is amended to add new requirements for Pediatric Intensive Care Units (PICU), which must be approved by the Department. This includes staffing and pediatric advanced life support training (PALS) requirements. The PICU must have a minimum average annual pediatric patient admission number of 200 per year.

Enclosed with this letter is a Frequently Asked Questions document to assist you with implementation. Should you have any questions, please contact me at (518) 402-1004.

Sincerely,

Ruth Leslie
Director
Division of Hospitals and Diagnostic Treatment Centers

Parent's Bill of Rights

As a parent, legal guardian or person with decision-making authority for a pediatric patient receiving care in this hospital, you have the right, consistent with the law, to the following:

- To inform the hospital of the name of your child's primary care provider, if known, and have this information documented in your child's medical record.

- To be assured your hospital will only admit pediatric patients to the extent consistent with your hospital's ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients.

- To allow at least one parent or guardian to remain with your child at all times, to the extent possible given your child's health and safety needs.

- That all test results completed during your child's admission or emergency room visit be reviewed by a physician, physician assistant, or nurse practitioner who is familiar with your child's presenting condition.

- □hat your child not to be discharged from our hospital or emergency room until any tests that could reasonably be expected to yield critical value results are reviewed by a physician, physician assistant, and/or nurse practitioner and communicated to you or other decision makers, and your child, if appropriate. Critical value results are results that suggest a life-threatening or otherwise significant condition that requires immediate medical attention.

- □hat your child not to be discharged from our hospital or emergency room until you or your child, if appropriate, receives a written discharge plan, which will also be verbally communicated to you and your child or other medical decision makers. The written discharge plan will specifically identify any critical results of laboratory or other diagnostic tests ordered during your child's stay and will identify any other tests that have not yet been concluded.

- To be provided critical value results and the discharge plan for your child in a manner that reasonably ensures that you, your child (if appropriate), or other medical decision makers understand the health information provided in order to make appropriate health decisions.

- That your child's primary care provider, if known, to be provided all laboratory results of this hospitalization or emergency room visit.

- To request information about the diagnosis or possible diagnoses that were considered during this episode of care and complications that could develop as well as information about any contact that was made with your child's primary care provider.

- To be provided, upon discharge of your child from the hospital or emergency department, with a phone number that you can call for advice in the event that complications or questions arise concerning your child’s condition.

Q&A FOR REVISIONS TO PART 405 REGULATIONS

MARCH 2014

Q1: Does this new regulation apply to only pediatric patients?

A1: No. These provisions specify (Section 405.1 Introduction) that they apply to patients of all ages, including newborns, pediatric and geriatric patients. There are specific provisions that apply only to pediatrics, such as those regarding pediatric intensive care units and medication dosing in children.

Q2: Why do these provisions require hospitals to provide the Department of Health (DOH) with a written report whenever certain individuals licensed by DOH lose hospital employment or privileges for certain reasons?

A2: Section 405.3 (Administration) currently requires hospitals to provide to the State Education Department (SED) a written report when enumerated professionals licensed by SED lose hospital employment or privileges for certain reasons. There were no such provisions for DOH licensed individuals. This regulation now also requires hospitals to furnish to DOH within 30 days of occurrence, a written report of any denial, withholding, curtailment, restriction, suspension, or termination of any membership or professional privileges in employment, by or any type of association with a hospital relating to an individual who is a health profession student serving in a clinical clerkship, an unlicensed health professional serving in a clinical fellowship or residency, or an unlicensed health professional practicing under a limited permit or a state license such as a medical laboratory technologist, radiologic technologist, radiologist assistant, respiratory therapist, or respiratory therapy technician for the following reasons:

- Alleged mental or physical impairment, incompetence, malpractice, misconduct or endangerment of patient safety or welfare;
- Voluntary or involuntary resignation or withdrawal of association, employment or privileges with the hospital to avoid imposition of disciplinary measure; and
- Receipt of information concerning a conviction of a misdemeanor or felony.

Q3: What are the quality assurance requirements for this regulation?

A3: Prior to these amendments, Section 405.6 (Quality Assurance Program) provisions specified that the activities of the quality assurance committee must involve all patient care services and include a review of the care provided by the medical, nursing staff and other health care practitioners employed by or associated with the hospital. These provisions retain this and add requirements that such review must include a determination that the hospital is admitting only those patients for whom it has appropriate staff, resources and equipment and transferring those patients for whom the hospital does not have the capability to provide care, except under conditions of disasters and/or emergency surge that may require admissions to provide care to those patients

More information and guidance for the clinician rendering pediatric care can be found at: **American Academy of Pediatrics Society of Critical Care Medicine: Admission and Discharge Guidelines for**

the Pediatric Patient Requiring Intermediate Care. *Pediatrics* 2004;113;1430-1433 (http://www.pediatrics.org/cgi/content/full/113/5/1430).

Q4: What has changed with regard to surgical services as a result of these revisions?

A4: Section 405.12 (Surgical Services) has been amended to specify that if a hospital provides surgical services it shall develop, keep current and implement effective written policies and procedures. These should include staff privileges, consistent with the provisions in section 405.4 (Medical Staff), concerning privileging and credentialing practitioners who perform surgical procedures, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care. The policies and procedures must be reviewed and updated as necessary, but at a minimum biennially. These provisions also specify that the hospital must assure the surgical privileges granted are commensurate with the practitioner's training and experience. This provision also adds references to the post anesthesia care unit (PACU), removes outdated terms and adds the requirement that the equipment must be age and size appropriate.

Q5: What has changed with regard to anesthesia services as a result of these revisions?

A5: As with the surgical services provisions, the anesthesia services provisions in Section 405.13 (Anesthesia Services) have been amended to specify that if a hospital provides anesthesia services it shall develop, keep current and implement effective written policies and procedures regarding staff privileges, consistent with the provisions in section 405.4 (Medical Staff) regarding the privileging and credentialing of practitioners that administer anesthetics, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care. The policies and procedures must be reviewed and updated as necessary, but at a minimum biennially. These provisions also specify that all equipment and services provided shall be age and size appropriate.

Q6: In regards to the Pediatric Advanced Life Support (PALS) training requirement, are board certified/board eligible emergency medicine physicians required to be current in PALS?

A6: The Department intends that ALL practitioners, regardless of whether they are board-eligible or board-certified or have training in a non-emergency based specialty, be current in PALS.

Q7: In regards to the Pediatric Advanced Life Support (PALS) training requirement what is considered current training in PALS?

A7: PALS must be taken every two years to maintain certification. "Current" means that PALS or any equivalent training or experience must be successfully completed a minimum of once every two years.

Q8: Is the Emergency Nursing Pediatric Course (ENPC) an equivalent to PALS?

A8: Training or experience which is "equivalent" should include the same key training as PALS, i.e, resuscitation, advanced life support and critical care management during respiratory/cardiopulmonary distress or arrest. The Department has determined that the Emergency Nursing Pediatric Course is equivalent to PALS for registered professional nurses (RNs) only. ENPC training is offered every four years. Since PALS requires recertification every two years RNs must complete PALS two years after they have completed ENPC or retake ENPC every two years. ENPC is only appropriate for RNs that will be providing nursing care within the scope of practice of a registered professional nurse. Nurse practitioners acting as mid level practitioners must complete PALS training.

Q9: Is the Advanced Pediatric Life Support (APLS) course an equivalent training to PALS?

A9: It depends, as the curriculum is designed to be flexible to the needs of the target audience. The target audience for APLS is physicians, and any other health care provider who is involved in the treatment of pediatric patients, especially in urgent or emergency care settings- nurses, physician assistants, paramedics, and other allied health professionals.

APLS can be completed in a 2-day schedule or it may be tailored by the instructor. For example there is a 1-day course option with prescribed self-study (designed to help reduce the time and expense of conducting a multi-day course in the classroom).

In order to meet the PALS equivalency of these regulation requirements APLS must be taught/delivered in the 2+ day format. PALS course completion cards may be issued for APLS Courses that meet the following criteria: (Source:http://www.aplsonline.com/about/pals.aspx)

- At least one faculty member must be a PALS instructor.
- The course must be registered as a PALS Provider renewal course with an approved AHA Training Center.
- The PALS instructor must administer the PALS post-test, grade the tests, remediate according to PALS requirements, and submit the required roster to the AHA training center.
- **The following components/requirements must be added to the recommended 2-day APLS Course Schedule in order to qualify for PALS Renewal option:** o **Review of the PALS Science Overview (25 minutes)** o **Complete CPR Competency Testing (20 minutes)** o **Resuscitation Team Concept DVD (20 minutes)** o **PALS Core Case Testing with individual team leader practice in both Cardiac and Respiratory/Shock (60 minutes)**
    - o **Students who would like to participate in the PALS Provider renewal course must have successfully completed the original PALS course within the past 2 years and will need to supply their valid PALS card.**

Q10: What does the Parent's Bill of Rights include? Will DOH be supplying a required format for this?

A10: Each hospital is required to post in a conspicuous place and provide a pediatric patient's parent or other medical decision maker with a copy of a "Parent's Bill of Rights" advising that, at a minimum and subject to laws and regulations governing confidentiality, that in connection with every hospital admission or emergency room visit: 1) The hospital must ask each patient or the patient's representative for the name of his or her primary care provider, if known, and shall document such information in the patient's medical record. 2) The hospital may admit pediatric patients only to the extent consistent with their ability to provide qualified staff, space and size appropriate equipment necessary for the unique needs of pediatric patients. 3) To the extent possible given the patient's health and safety, the hospital shall allow at least one parent/guardian to remain with the patient at all times.
Yes, the Department of Health has a required format which is attached and can be found on the DOH website. (ATTACH BILL OF RIGHTS HERE)

Q11: What are the requirements for provision of tests results to patients and/or their health care providers prior to discharge?

A11: All test results completed during the patient's admission or emergency room visit must be reviewed by a physician (MD), physician assistant (PA) or nurse practitioner (NP) who is familiar with the patient's presenting condition. This practitioner must have been directly involved in the patient's care and decision making or has assumed care of this patient.

Patients may not be discharged from the hospital or the emergency room until any tests that could reasonably be expected to yield "critical value" results – results that suggest a lifethreatening or otherwise significant condition such that it requires immediate medical attention – are reviewed by an MD, PA or NP and are communicated to the patient, his or her parents or other decision-makers, as appropriate.

Q12 Do the results of all ordered tests need to be reviewed before the patient is discharged?

A12: The ordering/treating practitioner will need to determine what test results need to be reviewed before the patient can be discharged based on the patient's presenting condition. It is acknowledged that some tests may not be completed during the patient's stay in the emergency department. However, the treating/ordering practitioner must use his or her clinical judgment to determine what test results are of such a critical nature that they must be reviewed prior to the patient's discharge. Hospitals must also have policies and procedures in place for both the communication of critical value tests that will be reviewed, as well as those non-critical value tests that will not be completed and will not be reviewed by a practitioner prior to discharge.

Q13: What information needs to be provided to the patient or parents' at the time of discharge?

A13: The patient/parent should be provided with telephone number/contact information in case there are any further questions or complications following discharge; information about the diagnoses that have been considered; potential complications; and diagnostic tests that were obtained. They should also be informed of any diagnostic testing that is still pending as well as information about contact with the patient's primary care provider and the information that was shared with that provider.

Patients may not be discharged until they receive a written discharge plan, which will also be verbally communicated to patients, their parents or other medical decision-makers. This plan must identify critical results of laboratory or other diagnostic tests ordered during the patient's stay and identify any other tests that are still pending. The discussion of this information must be accomplished in a manner that is understandable to the patient, their parents or other medical decision makers so that they may make appropriate health decisions.

Q14: Do hospitals have to provide all laboratory results to the patient's primary care provider after discharge from an inpatient admission?

A14: No. It is DOH's expectation that providers will make a reasonable attempt to identify the patient's primary care provider. If known, it is DOH's expectation that in addition to the discharge summary only those test results that yield critical value findings/results that will impact the primary care provider's subsequent treatment of the patient, as determined by the discharging provider, are required to be sent to the primary care provider.

Q14-A: Do hospitals have to provide all laboratory results to the patient's primary care provider on discharge from the emergency department?

A14-A: It is DOH's expectation that providers will make a reasonable attempt to identify the patient's primary care provider and if known, provide either all tests results or results that yield critical value findings that will impact the primary care provider's subsequent treatment of the patient as determined by the discharging provider.

Q15: If a patient's primary care provider is known and has access to the hospital's electronic health record (EHR) system, what are the DOH's expectations for transfer of lab results?

A15: If a patient's primary care provider can be notified and/or provided results through the EHR system established by the hospital, this would fulfill the intent of regulation. Hospitals do not have to mail a hard copy of the results to the primary care provider if secure electronic means are available through the EHR.

Q16: How does the Department define "critical value?" and what guidance is provided on how a hospital determines what tests met those criteria? Will DOH be providing a list?

A16: The regulation defines critical value as a result that if not treated could result in a lifethreatening or otherwise significant medical condition that requires immediate medical attention. Hospitals must implement a policy regarding compliance with this regulation. The decision regarding critical results is a medical judgment and must be made on an individual basis as it relates to the patient's presenting condition.

Q17: What has changed with regard to respiratory services as a result of these revisions?

A17: Section 405.14 (Respiratory Services) adds language that requires all equipment and services provided must be age and size appropriate.

Q18: What are the pharmacy amendments?

A18: Section 405.17 (Pharmaceutical Services) is amended to address the prevention of medical errors and patient safety. This requires hospital pharmacy directors, in conjunction with designated members of the medical staff, to ensure that for patients of all ages, weight must be measured in metrics and that up-to date resources relating to drug interactions, drug therapies, side effects, toxicology, dosage, indications for use, and routes of administration are available to the professional staff. Pediatric dosing resources must include age and size appropriate fluid and medication administration and dosing. Dosing must be weight based (or in emergencies, length based), should include the calculated dose, the dosing determination, such as the dose per weight (e.g., milligrams per kilogram) or body surface area, to facilitate an independent double-check of the calculation, and not exceed adult maximum dosage.

The amendments will also require the director to ensure that the pharmacy quality assurance program include monitoring and improvement activities to identify, measure, prevent and/or mitigate adverse drug events, adverse drug reactions and medication errors in accordance with generally accepted standards and practices in the field of medication safety and quality improvement. All drugs and biologicals must be controlled and distributed in accordance with written policies and procedures to maximize patient safety and quality of care.

Q19: Why are there requirements that all patients be measured in metrics and all dosing use the metric system?

A19: Currently, many medical facilities in the USA use the US customary, imperial units and/or the English unit system, as well as the metric system, for measurements. There have been medical errors due to patient weight being recorded in pounds, when this was interpreted as kilograms and oral medication errors because of confusion between ounces, teaspoons and milliliters. The patient safety community has recommended that the USA exclusively adopt the metric system for patient dosing. Facilities should use only metric units for all dosing instructions, including directions incorporated in prescribing and pharmacy computer systems. Dosing for oral medications should not use household measures, such as teaspoons. For more information on how to prevent medication errors see The Institute for Safe Medication Practices website at www.ismp.org.

Q20: What are the outpatient services' amendments?

A20: Section 405.20 (Outpatient Services) provisions adds language to clarify that outpatient services, including ambulatory care services and extension clinics need to be provided in a manner which safely and effectively meets the needs of all patients. Written policies must be in place for admission of patients whose postoperative status prevents discharge and necessitates inpatient admission to a hospital capable of providing the appropriate level of care. It also adds language allowing that parents, legal guardians and health care agents may receive discharge instructions, in addition to patients.

Q21: Why are there provisions in this regulation regarding social services?

A21: Section 405.28 (Social Services) is updated to reflect current standards that care be provided under the direction of a qualified social worker who is licensed and registered by the New York State Education Department to practice as a licensed master social worker (LMSW) or licensed clinical social worker (LCSW), within the scope of practice defined in Article 154 of the Education Law.

FAQ for PEDIATRIC INTENSIVE CARE UNIT (PICU) REQUIREMENTS

Q22: What defines a PICU?

A22: A PICU provides intensive care to pediatric patients (infants, children and adolescents) who are critically ill or injured. A PICU is a physically separate unit that provides multidisciplinary definitive care for a wide range of complex, progressive, and rapidly changing medical, surgical, and traumatic disorders occurring in pediatric patients. A PICU must be staffed by qualified practitioners competent to care for critically injured or injured pediatric patients.

Q23: Does the PICU have to be approved by the Department?

A23: Yes. For hospitals that currently do not have PICU beds listed on their operating certificate (OC), and/or there is some discrepancy in how the beds are listed, they must submit a certificate of need (CON) application through the New York State Electronic CON (NYSECON) system. The Department may visit and verify the services of each PICU unit as part of the CON approval process. If you currently have PICU beds listed on your OC, DOH requests a verification letter, signed by the Chief Executive Officer, which attests that you are in compliance with the PICU regulatory standards. DOH reserves the right to evaluate PICU operations at any time to evaluate compliance with the new regulations. The Department may visit and verify the verification letter contents. This letter should be sent to Ruth Leslie, Director, Division of Certification and Surveillance, NYSDOH, 875 Central Ave, Albany NY, 12206.

Q24: What happens if my PICU does not meet the new requirements of 405.22(b)?

A24: Hospitals that have PICU beds listed on their OC will receive a separate communication with a request to evaluate current operations in the context of the new regulations and to attest to compliance with them. If a hospital determines that they cannot meet the new regulations after assessing current operations, the hospital must submit a CON to decertify the service.

Q25: How does DOH differentiate a PICU from a special care unit, such as a pediatric cardiac stepdown unit?

A25: DOH recognizes medical/surgical beds and PICU beds, but does not recognize a category of inpatient beds called special care units. As such, there are no regulations that dictate care in this type of bed. Depending upon the care provided in these special care beds, they may be considered medical/ surgical or PICU. These regulations clarify that hospitals shall only admit patients consistent with its ability to provide qualified staff, space, and size appropriate equipment. Hospitals should evaluate their current pediatric operations in the context of these new regulations to determine whether care delivered in these special care units rises to the level of the PICU requirements. If a hospital determines that their unit fits the criterion for a PICU, a hospital will need to file a CON to add PICU services to its the operating certificate.

Q26: Is a PICU required to be a physically separate unit?

A26: Yes. The Department expects this to be a separate defined space, a discrete unit for pediatric patients only, with walls and barriers apart from any other service.

Q26: What are the qualifications for the PICU physician Director?

A27: The PICU director shall be a board certified pediatric medical, surgical, or anesthesiology critical care/intensivist physician with specialized training and demonstrated competence in pediatric critical care.

Q27: What are the requirements for physician coverage and physical presence in the PICU??

A28: All hospitals with a PICU must have a physician, notwithstanding emergency department staffing, in-house, (not necessarily in the PICU) 24 hours a day who is available to provide bedside care to patients in the PICU. This physician must be a post graduate year three in pediatrics or anesthesiology. The PICU shall have, at a minimum, physically present, a physician at the level of a post graduate year two or above and/or a physician assistant and/or nurse practitioner with specialized training in pediatric critical/intensive care. An attending pediatric, medical, surgical, or anesthesiology critical care/intensivist physician must be available within 60 minutes to be physically present in the PICU if needed.

Q29: What are the qualifications for practitioners staffing the PICU?

A29: Qualified practitioners are staff functioning within his or her scope of practice according to State Education Law and who meet the hospital's criteria for competence, credentialing and privileging in the management of critically ill or injured pediatric patients.

For more information see **The American Academy of Pediatrics Society of Critical Care Medicine: Guidelines and Levels of Care for Pediatric Intensive Care Units.** David I. Rosenberg, M. Michele Moss, Section on Critical Care and Committee on Hospital Care, *Pediatrics* 2004;114;1114 DOI: 10.1542/peds.2004-1599 (http://pediatrics.aappublications.org/content/114/4/1114.full.html) These guidelines were used as a resource to develop the regulations.

Q30: Are there specific training requirements for PICU staff?

A30: All physician and nursing staff shall have completed and be current in pediatric advanced life support (PALS), or have current training or experience equivalent to PALS. (See also questions 6 and 7).

Q31: Are quality assessment performance improvement (QAPI) activities required of PICU services?

A31: Yes. QAPI activities, which includes the active participation by all clinical members of the PICU team is required. QAPI activities should include monitoring of PICU volume and patient health outcomes, morbidity and all case mortality review, and regular multidisciplinary conferences to include all staff involved in the care of PICU patients.

Q32: Is there a pediatric patient volume requirement to have a PICU?

A32: Yes. A PICU must have at least 200 annual admissions to meet the required threshold to have a PICU.

Q33: If there are PICU staffing problems, is a hospital required to notify the Health Department?

A33: Yes. A hospital must notify the Health Department in writing within 7 business days of any significant changes in its PICU services, such as, but not limited to: (a) any temporary or permanent suspension of services, or (b) difficulty meeting staffing or workload requirements. This notice should be sent to Ruth Leslie, Director, Division of Certification and Surveillance, NYSDOH, 875 Central Ave, Albany NY, 12206.

FAQ FOR RADIOLOGY/IMAGING REQUIREMENTS

Q34: What would a policy/procedure regarding imaging studies for newborns/pediatric patients include?

A34: A policy should include:

- Standards for clinical appropriateness;
- Appropriate radiation dosage and beam collimation;
- Image quality and patient shielding;
- A specific policy and a procedure shall be developed to ensure that the practitioner's order for an imaging study is specific as to the body part(s) that are to be imaged.

This requirement can be met by updating your existing policy and procedure manual to include policies addressing these issues and ensuring that they have both adult and pediatric examination procedures.

Q33: Does a facility have to create its own criteria or is it acceptable to use the American College of Radiology (ACR) or other accepted medical standards?

A33: ACR or another medical society's appropriateness criteria will be accepted or you may develop your own. Any criteria should be *based on generally accepted standards of medical care??*

Q34: What are the requirements for physicians who administer fluoroscopy?

A34: The chief of radiology, in conjunction with the radiation safety officer, shall ensure that all practitioners who utilize ionizing radiation equipment within the hospital are properly trained in radiation safety procedures for patients of all ages. The training given to physicians using fluoroscopy must include and document that all operators (physicians) have basic radiation safety training and are familiar with facility policies and procedures.

Q35: Are electronic images required to be backed up and if so, does this have to be located in an area separate from the primary storage devices?

A35: Yes. All electronic images shall have duplicate storage either offsite or in another area of the hospital separate from the primary storage devices. The Department expects the facility to demonstrate how they are backing up, and verifying all images. This will be reviewed at the time of inspection.

Q36: How does the Department determine the number of staff full time New York State licensed radiation therapists which are "sufficient to meet the needs of the service"?

A36: This is evaluated based on number of linear accelerators (LINACS), current patient load (both volume and complexity) and any problems or issues.

Q37: The regulations require that a CT scanner be available within the radiation therapy program that is equipped for radiation oncology treatment planning or arrangements shall be made for access to a CT scanner on an as needed basis and that provisions shall be made for access to an MRI scanner for treatment planning purposes on an as needed basis. Does this mean a facility would need to purchase and obtain a certificate of need (CON) for a CT and MRI if they do not currently have one? Or is it permissible to enter into a contract with a radiology provider either on-site or off site?

A37: Contracting of services to meet this requirement is acceptable. The Department would expect this to be in a written, formal agreement, and expect to be able to review these documents during an inspection.