



Regulatory Compliance Associated With Contrast Media

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The credit earned from the Quick Credit test accompanying this article may be applied to the AHRA certified radiology administrator (CRA) operations management domain.



E X E C U T I V E

S U M M A R Y

- A basic understanding of the role of regulatory agencies in governing the healthcare environment and their influence over contrast media use is required of radiographers and imaging administrators to meet the many standards of compliance. In addition, radiology management teams must consider cost effectiveness, departmental efficiency, workplace safety, and compliance in choosing to implement new products.
- Regulatory agencies may be classified into 2 groups, voluntary and involuntary. Involuntary agencies are governmental agencies mandating regulatory compliance by local, state, or federal laws. Voluntary agencies are precisely that, those agencies an institution voluntarily chooses to participate with, to demonstrate the quality of care they provide.
- Failure to follow involuntary regulatory guidelines or to participate in voluntary best practice standards jeopardizes patient safety and the quality of care provided, and exposes the institution and the individual to liability risks. Severe penalties may result from a failure to maintain regulatory compliance, including the possibility of large fines, criminal indictments, and loss of third-party reimbursement.
- Achieving regulatory compliance is never an easy venture with the number of regulatory agencies and standards needing to be addressed. Combining regulatory compliance with the effects of doing business provides quite a challenge for today's imaging departments. A solid knowledge base in regulatory standards along with continuous investigation of new standards will allow departments to evaluate their own processes involved in providing patient care. Recognition of areas of high risk/high volume, including contrast media use, will assist in directing the departments' focus appropriately. A thorough evaluation of the products used and their respective handling and administration, in regard to patient and workplace safety, and appropriate documentation of workplace injuries due to contrast media packaging, will assist in maintaining a high level of compliance.

Imaging departments today are the targets of greater focus for regulatory surveys, due in part to advanced imaging technologies and homeland security initiatives with radiopharmaceuticals. Expanded regulatory standards address a host of practices within the department of imaging services. Contrast media, which is considered diagnostic pharmaceutical, is just one area requiring special attention to maintain regulatory compliance in the department.

A basic understanding in the role of regulatory agencies in governing the healthcare environment and their influence over contrast media use is required of radiographers and imaging administrators to meet the many standards of compliance. In addition, radiology management teams must consider cost effectiveness, departmental efficiency, workplace safety, and compliance in choosing to implement new products.

Classification and Types of Regulatory Agencies

Regulatory agencies may be classified into 2 groups, voluntary and involuntary. Involuntary agencies are governmental agencies mandating regulatory compliance by local, state, or federal laws. Voluntary agencies are precisely that, those agencies an institution voluntarily chooses to participate with, to demonstrate the quality of care they provide.

The Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the Center for Medicaid and Medicare Services (CMS) are examples of involuntary regulatory agencies. The CDC is the principal agency responsible for protecting the health and safety of the American public.¹ Under the jurisdiction of the Department of Labor, OSHA creates and enforces workplace safety and health regulations,² while NIOSH, part of the CDC in

the Department of Health and Human Services, ensures the safety and healthful working conditions of the public through research, education, information, and training.³ The CMS is responsible for establishing quality standards in healthcare through survey and certification processes, including clinical laboratory quality standards and the 1996 Health Insurance Portability and Accountability Act (HIPAA) enforcement.⁴

Voluntary regulatory agencies include professional colleges or organizations like the American College of Radiology (ACR) and the American Society of Radiologic Technologists (ASRT). These organizations establish best practice standards through the peer review process. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the accrediting body most commonly used by hospitals in the United States.⁵ JCAHO establishes standards through survey, sentinel event reporting, and root cause analysis processes.

Failure to follow involuntary regulatory guidelines or to participate in voluntary best practice standards jeopardizes patient safety and the quality of care provided, and exposes the institution and the individual to liability risks. Severe penalties may result from a failure to maintain regulatory compliance, including the possibility of large fines, criminal indictments, and loss of third-party reimbursement.

All types and forms of contrast agents are classified as pharmaceuticals,⁶ and accordingly are listed in the National Drug Code⁷ and must meet the requirements of the Food and Drug Administration (FDA). All regulatory agencies require monitoring of pharmaceuticals by a licensed pharmacist and dispensing by a licensed physician. Use of contrast media

in the imaging department must meet all the same regulatory guidelines as does use of other pharmaceuticals, including product labeling, packaging safety, and storage and handling.

Contrast media manufacturers label their products and provide package inserts according to FDA regulations.⁸ The product label must include the brand and/or generic name of the pharmaceutical, the strength, quantity, national drug code number, and expiration date. The manufacturer's package insert provides a wealth of information for the consumer including indications for use, contraindications, adverse events, and storage and handling recommendations.

JCAHO Compliance Associated With Contrast Media Use

The JCAHO's *Comprehensive Accreditation Manual for Hospitals* describes the agency's goals and requirements.⁹ Each standard is explained in detail through elements of performance. The JCAHO is respectful of all other regulatory agencies and often defers to them when another agency's regulations take precedence. The JCAHO National Patient Safety Goals (NPSG) and 3 sections of the standards most directly, but not solely, impact the use of contrast media. Two such standards, NPSG 2 and 3, have been expanded for 2006 (Table 1). The Environment of Care, Medication Management, and Care of Patients sections of the standards provide insight into regulations regarding contrast media use.

JCAHO, through sentinel event reporting, identifies unsafe practices, for example an increase in medication errors resulting from pharmaceuticals

Table 1. JCAHO 2006 National Patient Safety Goals and Requirements.

<u>NPSG Goal</u>	<u>New or Expanded Requirement</u>
2. Improve the effectiveness of communication among caregivers.	2E. Implement a standardized approach to "hand off" communications, including an opportunity to ask and respond to questions.
3. Improve safety of using medications.	3D. Label all medications, medication containers (eg, syringes, medicine cups, basins), or other solutions on and off the sterile field in perioperative and other procedural settings.
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Expanded regulatory standards address a host of practices within the department of imaging services. Contrast media, which is considered diagnostic pharmaceutical, is just one area requiring special attention to maintain regulatory compliance in the department.

being removed from their original containers and placed in unlabeled containers, such as cartridges for power injectors, or into sterile bowls. This can occur during some procedures, including those performed in the interventional radiology or the cardiac catheterization laboratories.¹⁰

NPSG No.3 requiring improvement in the safe use of medications, expands in 2006 to include the labeling of medications when they are transferred from the original package to another container, both on and off the sterile field, even if only one medication is being used. Labels must include the name and strength of the medication or solution, the date, and the initials of the person preparing the label. Labels may be commercially obtained, as in the case of sterile labels, or developed by the individual facility. Any unlabeled medication should be immediately discarded to ensure patient safety.

According to JCAHO Standard MM.2.20, Element of Performance #3, unauthorized persons, in accordance with the hospital's policy and law or regulation, cannot obtain access to medications.⁹ Standard MM.5.10, Element of Performance #1, policies and procedures, addresses healthcare staff who are allowed to administer medications, with or without supervision, consistent with law or regulation and hospital policy.⁹ The JCAHO is currently conducting surveys in the author's 4-hospital/24 ambulatory center system. In each imaging area, the physician surveyor and the EOC surveyor have requested to see where we store contrast (not only injectable contrast agents but barium as well), how it is secured, and who has access. They specifically asked about contrast warmers and refrigerators, and were very interested in the duties of housekeeping staff in these areas.

The manufacturer's recommendations and the JCAHO environment of care standards should be followed for appropriate storage and handling of contrast materials. All contrast media storage areas and contrast media warmers require locked security, allowing access only to appropriate staff. Stock should be rotated and expiration dates monitored. Shipping cartons should be removed and stock should be located on shelving no higher than 18 inches from the

ceiling. Floors must be kept clear to facilitate thorough cleaning.

Standard MM.4.10 requires medication evaluation by a pharmacist prior to dispensing for the appropriateness of the drug therapy and dosage, analysis of possible drug interactions, and determination of patient allergy history. "Pharmacists review each prescription or order for medication and contact the prescriber or orderer when questions arise (except when a licensed independent practitioner with appropriate clinical privileges controls prescription or ordering, preparation, and administration, as in endoscopy or cardiac catheterization laboratories, surgery, or during cardiorespiratory arrest, and for some emergency orders when time does not permit)."¹¹ This standard is of particular importance if contrast media is being administered outside the department of imaging. Contrast-enhanced procedures performed in the radiology department fall under the supervision of the radiologist and do not require review by a pharmacist. However, contrast media supplied to a nursing unit, for example an oral agent for an abdominal CT scan, does require a pharmacist review prior to administration.¹² Standard IM.6.20 requires documentation of all administered medications in the medical record according to the facilities policies.

A specific written order for contrast media administration may also be required depending on state regulations. NPSG requirement No. 2A emphasizes the need for a "read-back" when verbal orders are received for diagnostic tests and contrast media administration. According to this goal, the receiver should write down the complete order and then read it back to confirm the information given.

Requirement No. 2B addresses the use of inappropriate abbreviations. The JCAHO has established an official "Do Not Use" list of dangerous abbreviations, acronyms, and symbols (Table 2) and requires each facility to add these to their own identified list. Care should be demonstrated when writing or giving verbal orders for diagnostic procedures or contrast media administration to ensure appropriate abbreviation use. Finding one unapproved abbreviation in a

Table 2. JCAHO Official "Do Not Use" List of Abbreviations, Acronyms, and Symbols.*

<u>Do Not Use</u>	<u>Potential Problem</u>	<u>Use Instead</u>
U (unit)	Mistaken for "0" (zero), the number "4" (four), or "cc"	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "International Unit"
Q.D., QD, q.d., qd (daily)	Mistaken for each other	Write "daily"
Q.O.D., QOD, q.o.d., qod (every other day)	Period after the Q mistaken for "1" and the "O" mistaken for "1"	Write "every other day"
Trailing zero (X.0 mg) [†]	Decimal point is missed	Write X mg
Lack of leading zero (.X mg)		Write 0.X mg
MS	Can mean morphine sulfate or magnesium sulfate	Write "morphine sulfate"
MSO ₄ and MgSO ₄	Confused for one another	Write "magnesium sulfate"
<p>*Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms.</p> <p>[†]Exception: A "trailing zero" may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.</p> <p>Reproduced with permission from JCAHO Web site (http://www.jcaho.org/accredited+organizations/patient+safety/dnu.htm)</p>		

medical record constitutes one type I recommendation on the facilities survey results.

The addition of requirement No. 2E for 2006, stipulates the implementation of a standardized approach to "hand off" communication. The purpose of this goal is to ensure the next care provider receives accurate information regarding the services, care, or treatment given to the patient. Communication of diagnostic imaging procedures and contrast media administration according to the facilities processes will be required to fulfill this goal. NPSG No. 8A requires implementation of a process for obtaining and documenting a complete list of the patient's current medications including all prescription medications, sample medications, herbal supplements, vitamins and minerals, contrast agents, radiopharmaceuticals, and others as outlined in the accreditation manuals.¹³ Goal No. 8B mandates the complete reconciled medication list is communicated to the next healthcare provider, whether within the

same facility or not. This requirement is necessary for a change in service areas, healthcare provider, or level of care when orders are rewritten.

The administration of contrast media presents potential reactions or adverse events for all patients, although these situations are greatly reduced with the use of low osmolar (LOCM) or isosmolar (IOCM) contrast media. Both LOCM and IOCM are recommended for use in patients with renal impairment.¹⁴ MM.6.20 standard specifies that the hospital responds appropriately to adverse medication events or errors. Compliance with this standard ensures documentation of adverse events according to hospital policy and governing laws, and requires evaluation of the appropriateness of the medical response to the adverse event.

Anticipating scoring of the JCAHO standards during the site survey can sometimes be a confusing issue. Accredited facilities are allowed 9 type I findings or recommendations during a survey before accreditation is

Table 3. JCAHO Standards Scoring.

<u>Scoring Category</u>	<u>Description</u>	<u>Citation</u>
Category A	Met or not met (Yes or No) standard	One type I recommendation for each not met citation
Category B	Presence or absence of compliance. Evaluation of processes.	0=not met 1=some of the requirements met with process design 2=met the requirements with process design
Category C	Evaluates practice trends	Three citations in one standard scored under category C=1 type I recommendation

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in jeopardy. Scoring is broken down by category (A, B, and C), each providing different types of evaluation (Table 3). All the National Patient Safety Goals fall under category A scoring, indicating finding one failure of compliance during survey yields one type I recommendation or finding. Category B scoring involves 2 steps of evaluation to determine the presence or absence of compliance. Category C scoring evaluates practice trends. Three citations of a particular standard, for example finding areas of high dust accumulation, would result in one type I recommendation through category C scoring.

Use of Contrast Media Warmers

The warming of contrast agents is recommended by some manufacturers to bring contrast media to a temperature and viscosity closer to that of blood.¹⁵ Contrast media warmer temperatures should be established according to the manufacturer's recommendations. Daily monitoring and documentation of warmer temperatures is required, and the appropriate threshold for corrective action must be indicated on the documentation log. Warmers whose temperatures exceed threshold limits must have corrective action documented and should be rechecked in 1 hour to ensure actions have been effective. Staff should be aware that expiration dates may change with warming. Contrast agents typically are stable for 30 days with warming.

Workplace Safety Concerns

Product containers should be evaluated for safety concerns in regard to sharps injuries and proper waste dis-

posal. Glass product packaging is considered a type of sharp, whether intact or broken. Broken glass contrast media bottles or their metal rings are common causes of sharps injuries in the imaging department. All regulatory agencies, especially OSHA, require documentation of staff injuries and appropriate follow-up as provided to the individual(s).¹⁶⁻¹⁸ Identified trends in sharps injuries will require further investigation and analysis, and severe wounds may subsequently require reporting to the state OSHA branch.

Glass packaging presents a special challenge with waste disposal. Broken glass must be cleaned up with a broom and dustpan, never by hand, usually requiring the assistance of the facilities environmental services department. Time spent waiting for clean up can result in increased room down time, decreasing departmental effectiveness and productivity and adversely affecting patient and physician satisfaction levels.

Whether whole or broken, glass packaging must be disposed of in puncture-proof containers to eliminate the risk of injury during handling. In hospitals, puncture-proof containers usually are in the form of biohazard buckets. These containers are discarded with other medical refuse and greatly increase the cost of waste disposal, sometimes by as much as 10 times compared with regular trash removal. Contrast media is now available in a polymer bottle package, which can be discarded through regular disposal methods and because of its design and material does not present the hazards of breakage and associated injuries.

Table 4. Contrast Media Competency Criteria for Imaging Staff.

- Identifies types of contrast media available
- Identifies department policies for safe administration
- Identifies appropriate storage and handling of contrast media
- Verbalizes or demonstrates appropriate venipuncture techniques
- Verbalizes or demonstrates appropriate IV insertion techniques
- Recognizes criteria placing patients at high risk for contrast media administration
- Verbalizes and recognizes categories of allergic reactions and possible treatment options
- Verbalizes and recognizes other adverse events related to contrast media (eg, extravasations)
- Completes appropriate documentation of allergic reactions, adverse events, and injuries due to contrast media packaging as directed by department policy

Adjunct Safety Concerns Associated With Contrast Media

Ergonomics and latex allergies must be addressed when using contrast media.

Ergonomic Considerations

Ergonomics is defined as the scientific discipline devoted to the study and analysis of human work, especially as it is affected by individual anatomic, psychological, and other human characteristics.¹⁹ Workplace hazards can contribute to employee injuries such as repetitive stress or cumulative trauma disorders. Common problems are carpal tunnel syndrome, tendonitis, back pain, and injuries associated with muscles, joints, and nerves. Risk factors for ergonomic injuries include repetitive motion, improper body mechanics resulting in awkward postures, long durations of repetitive activity with a lack of recovery time between repetitions, or forceful body movements.²⁰ Vibration, uncomfortable environmental conditions, and a disorganized or stressful work environment may also be contributing factors to these conditions.²¹

Contrast media in polymer multiuse bottles provide more ergonomically friendly options for imaging departments. The lighter weight design of polymer packaging (up to 50% lighter than comparable glass products when full and 80% lighter when empty) reduces stress on muscles, joints, and tendons.²² Multiuse products afforded by polymer packaging reduce repetitive motions associated with high volume par levels of stock, and avoid the need for continuous preparation and handling of contrast media. Better organization of work and improved turn around times are recognized with the reduction in steps required for preparation of contrast media in multiuse vials.

Latex Allergies

Latex allergies also present a workplace safety concern, as well as an environmental concern for patients and visitors. The CDC reports 1%–6% of the general population and 8%–12% of healthcare workers who are regularly exposed to latex are sensitized.²³ Prolonged exposure to latex is the primary cause of sensitization and development of allergies.^{23–27} Workers in the rubber industry, people with spina bifida or urogenital anomalies, and healthcare workers are at greatest risk for sensitization,^{25,27} with healthcare workers shown as the fastest growing population to develop latex allergies according to the CDC.

Latex allergy reactions have a severity range of mild irritant contact dermatitis to death. The only known treatment option is complete avoidance of latex to prevent reactions and sensitization. The healthcare environment presents numerous sources for latex exposure. Adhesive tape, gloves, stethoscopes, blood pressure cuffs, endotracheal tubes, patient-controlled anesthesia syringes, and medication vial stoppers may all be sources of latex.^{24–26}

OSHA and JCAHO require facilities to provide a safe environment for staff, patients, and visitors. Eliminating latex from the environment improves workplace safety, but it is a daunting task. Continued development and implementation of latex-free products, as in the case of polymer-packaged contrast media, can eliminate additional exposure and lessen the risk of subsequent allergies.

Staff Competency in Contrast Media Use

Another important consideration in regulatory compliance of contrast media is training and competency of staff

A solid knowledge base in regulatory standards along with continuous investigation of new standards will allow departments to evaluate their own processes involved in providing patient care.

involved in contrast media use (Table 4). All regulatory agencies mandate and review the continuous evaluation and training of staff.

Types of contrast agents and department policies regarding the safe administration, storage, and handling of contrast media should be included in all new-hire orientation programs. Staff competency must be evaluated and documented according to the facilities' policies. Competency evaluation should include verbalization or demonstration of venipuncture and IV insertion techniques, safe storage and administration of contrast materials including recognition of the potential for allergies or complications, and appropriate documentation of contrast media use and adverse events.

In addition, it is important that staff be sensitized to the need to document injuries due to contrast media packaging regardless of the severity of the injury.

Conclusion

Achieving regulatory compliance is never an easy venture with the number of regulatory agencies and standards needing to be addressed. Combining regulatory compliance with the effects of doing business provides quite a challenge for today's imaging departments. A solid knowledge base in regulatory standards along with continuous investigation of new standards will allow departments to evaluate their own processes involved in providing patient care. Recognition of areas of high risk/high volume, including contrast media use, will assist in directing the departments' focus appropriately. A thorough evaluation of the products used and their respective handling and administration, in regard to patient and workplace safety, and appropriate documentation of workplace injuries due to contrast media packaging, will assist in maintaining a high level of compliance. 🌟

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Regulatory Compliance Associated With Contrast Media Home-Study Test



1.0 Category A credit • Expiration date 12-31-2007

Carefully read the following multiple choice questions. Mark your answers on the answer sheet found on page 28 and mail or fax the answer sheet to:

The credit earned from the Quick Credit test accompanying this article may be applied to the AHRA certified radiology administrator (CRA) operations management domain.



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Questions

Instructions: Choose the answer that is most correct.

- 1. What 2 factors today make imaging departments the targets of greater focus for regulatory surveys?**
 - a. Advanced imaging technologies and workplace safety issues
 - b. Homeland security initiatives with radiopharmaceuticals and advanced imaging technologies
 - c. Workplace safety issues and homeland security initiatives with radiopharmaceuticals
 - d. Contrast media usage and cost effectiveness related to the use of radiopharmaceuticals
- 2. Radiology administrators must consider which of the following when choosing to implement new contrast media products?**
 - a. Departmental efficiency
 - b. Workplace safety
 - c. Cost effectiveness
 - d. All of the above
- 3. Governmental agencies that mandate regulatory compliance by local, state, or federal laws are classified as:**
 - a. Involuntary regulatory agencies
 - b. Voluntary regulatory agencies
 - c. Workplace safety agencies
 - d. None of the above
- 4. Which of the following is an example of an involuntary regulatory agency?**
 - a. American College of Radiology (ACR)
 - b. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
 - c. The Centers for Disease Control and Prevention (CDC)
 - d. All of the above
- 5. Enforcement of HIPAA regulations is the responsibility of:**
 - a. The Occupational Safety & Health Administration (OSHA)
 - b. The Center of Medicaid & Medicare Services (CMS)
 - c. The American College of Radiology (ACR)
 - d. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- 6. Contrast media in the imaging department must meet all the same regulatory guidelines as other pharmaceuticals including:**
 - a. Packaging safety
 - b. Product labeling
 - c. Storage and handling
 - d. All of the above

7. **FDA regulations require that the product label on contrast media include:**
 - a. The expiration date
 - b. National drug code number
 - c. Contraindications
 - d. Both a and b
8. **Storage and handling recommendations for contrast media are usually found:**
 - a. In the manufacturer's package insert
 - b. In the department's policy manual
 - c. On the product label
 - d. All of the above
9. **The JCAHO National Patient Safety Goals (NPSG) and 3 sections of the standards most directly impact the:**
 - a. Manufacturing of contrast media
 - b. Packaging of contrast media
 - c. Use of contrast media
 - d. Labeling of contrast media
10. **NPSG No. 3 requiring improvement in the safe use of medications, expands in 2006 to include the labeling of medications when they are transferred from the original package to another container:**
 - a. On the sterile field
 - b. Off the sterile field
 - c. Only when multiple medications are being used
 - d. Both a and b
11. **Which of the following requires locked security?**
 - a. Contrast media storage areas
 - b. Radiographic rooms when contrast media is in use
 - c. Contrast media warmers
 - d. Both a and c
12. **When contrast media is supplied to a nursing unit outside the department of imaging:**
 - a. It falls under the supervision of the radiologist
 - b. It does not require review by a pharmacist
 - c. It does require review by a pharmacist
 - d. It falls under the supervision of the prescriber or orderer
13. **What agency has established an official "Do Not Use" list of dangerous abbreviations, acronyms, and symbols?**
 - a. JCAHO
 - b. CDC
 - c. CMS
 - d. OSHA
14. **NPSG No. 8A requires a process for obtaining a complete list of the patient's current medications including:**
 - a. Herbal supplements
 - b. All prescription medications
 - c. Contrast agents
 - d. All of the above
15. **The use of low osmolar or isosmolar contrast media greatly reduces:**
 - a. Storage and handling problems
 - b. Potential reactions for all patients
 - c. The need for contrast media warmers
 - d. The necessity for a review by the pharmacist
16. **During a survey by the JCAHO, an accredited facility is allowed:**
 - a. 9 type I recommendations
 - b. 1 type 9 recommendation
 - c. 3 type 2 recommendations
 - d. None of the above
17. **Some manufacturers recommend bringing contrast media to a temperature and viscosity closer to the of:**
 - a. Water
 - b. Blood
 - c. Body tissue
 - d. All of the above
18. **Glass packaging, whether whole or broken, must be disposed of in:**
 - a. Puncture-proof containers
 - b. Sterile buckets or trash cans
 - c. Regular trash cans
 - d. None of the above
19. **Contrast media in a polymer bottle package can be discarded through:**
 - a. Puncture-proof systems
 - b. Regular disposal methods
 - c. Sterile buckets
 - d. None of the above
20. **The scientific discipline devoted to the study and analysis of human work is defined as:**
 - a. Erudition
 - b. Ethnology
 - c. Ergonomics
 - d. Eugenics



ANSWER SHEET AHRA Home-Study Resources

Regulatory Compliance Associated With Contrast Media

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Indicate your answers to the post-test questions by entering the correct letter(s) on the lines provided.

Regulatory Compliance Associated With Contrast Media

- | | |
|-----------|-----------|
| 1. _____ | 11. _____ |
| 2. _____ | 12. _____ |
| 3. _____ | 13. _____ |
| 4. _____ | 14. _____ |
| 5. _____ | 15. _____ |
| 6. _____ | 16. _____ |
| 7. _____ | 17. _____ |
| 8. _____ | 18. _____ |
| 9. _____ | 19. _____ |
| 10. _____ | 20. _____ |

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