

2006 SS&D Workshop Pre-test

We have designed this pretest in an effort to better understand student needs, and to provide students with a means to gauge their understanding of the material. Please complete the pretest before arriving at class. Please fill out your answers clearly on BOTH the answer sheet and the pretest question sheet. Of the 62 questions, 11 have multiple correct answers. Answer sheets will be collected prior to the lectures on Monday morning.

PART I: General SS&D Questions

Choose all answers that apply, unless specifically directed otherwise.

- 1) You respond to a telephone call in which you are told that an applicant wants to distribute a product that will save lives. The product is a smoke detector that contains americium-241 and is designed to be a Christmas tree ornament. The applicant wants to distribute the product to person exempt from licensing requirements. The applicant asks to whom the application for an exempt distribution license (applicant has already filed for their possession license) should be sent. You respond by telling the applicant to send it to:
 - a) the Agreement State for which the applicant resides.
 - b) NRC.
 - c) the CRCPD.
 - d) none, it cannot be approved
- 2) A custom device is defined as a device that is:
 - a) built to unique specifications.
 - b) for use by the U.S. Customs Department.
 - c) expected to be distributed commercially.
 - d) designed to be used by a single user.
 - e) none of the above
- 3) An applicant provides you with an ANSI/HPS N43.6-1997 Classification of 96C22222. Based on what you know in general about the ANSI classification, and without referring to the ANSI Guide, which use is the source most likely designed for:
 - a) well logging.
 - b) static eliminators.
 - c) portable moisture and density gauges.
 - d) gamma gauges.
 - e) gamma irradiators.
 - f) none of the above

For questions 4-6 refer to the definition of an ANSI source classification. An example of an ANSI classification for a sealed source is 96C43515.

- 4) The first two digits represent:
 - a) year of approval of the standard that the performance tests are based on.
 - b) material designation of the source capsule.
 - c) year that the source was tested.
 - d) none of the above
- 5) The letter C:
 - a) indicates corrosion resistance.
 - b) designates capsule design.
 - c) designates activity level of the source.
 - d) designates the hardness.
 - e) none of the above
- 6) The last five digits represent the performance for:
 - a) temperature, corrosion, impact, pressure and vibration respectively.
 - b) hardness, temperature, corrosion, pressure and puncture respectively,
 - c) temperature, radiation levels at 5, 30, and 100 cm and corrosion respectively.
 - d) temperature, pressure, impact, humidity and puncture respectively.
 - e) none of the above
- 7) The principal use code, as defined in Regulatory Guides 10.10 and 10.11, is used to describe the predominant uses of sealed sources and devices. An applicant requesting a safety evaluation of a device is proposing to use a 1.5 curie, krypton-85 sealed source that is already registered by another distributor. Upon review of the sealed source registration certificate, you notice that the sealed source has a principal use code for beta gauges and the applicant's device uses bremmstrahlung. Based on this information, you should:
 - a) deny the application because the principle use code and description of typical use on the source registration certificate do not match the applicant's request.
 - b) determine if the proposed conditions of use of the device fall within the conditions of use listed in the source certificate.
 - c) consider the dimensions and tolerances to determine if the source fits in the device.
 - d) determine if the source capsule and the device materials of construction are compatible under the proposed conditions of use.
 - e) none of the above
- 8) Quality control may be defined as (*choose the best answer*):
 - a) the means to control and measure characteristics of an item, process or facility to established requirements.
 - b) making sure the product works.
 - c) none of the above

- 9) In general, if a licensee wants to use a specifically licensed sealed source or device,
- a) the user is responsible for ensuring that the item is registered.
 - b) distributor is responsible for ensuring that the item is registered.
 - c) manufacturer is responsible for ensuring that the item is registered.
 - d) none of the above
- 10) Who maintains the Sealed Source and Device Registry?
- a) CRCPD
 - b) NRC
 - c) OAS
 - d) AECB
 - e) FDA
 - f) none of the above
- 11) You are reviewing the information that a vendor proposes to provide to its customers. Which item(s) below should you include in your review?
- a) instructions for safe operation and maintenance of the device
 - b) testing for proper operation of the "on-off" mechanisms and indicators
 - c) emergency procedures
 - d) instructions for return or disposal
 - e) warranty
 - f) none of the above
- 12) You are reviewing the conditions of use during a safety evaluation of a device. Which item(s) below should you consider during your review?
- a) operating conditions and environmental extremes (i.e., temperature, pressure, humidity)
 - b) intended users
 - c) how the device operates
 - d) life expectancy of the device
 - e) none of the above
- 13) You are reviewing a sample label that an applicant is proposing to use on their device. Which items below would you consider in making your determination that the label is acceptable?
- a) location
 - b) content
 - c) ornamental quality
 - d) method of attachment
 - e) size and materials of construction
 - f) none of the above

Questions 14-18 refer to the definition of the registration certificate number (i.e., NR-0202-D-101-S). For these questions, use the generic registry number AA-BBBB-C-DDD-E.

14) AA defines

- a) the state abbreviation code or NR for NRC which signifies where the manufacturer is located.
- b) the state abbreviation code or NR for NRC which signifies where the distributor is located.
- c) the state abbreviation code or NR for NRC which signifies which regulatory body performed the review.
- d) none of the above

15) BBBB defines:

- a) a unique number assigned to the distributor/vendor of the product.
- b) a unique number assigned to the manufacturer of the product.
- c) the product number.
- d) none of the above

16) C defines:

- a) the license code.
- b) the radionuclide group.
- c) the principal use code.
- d) whether the product is a source, device, or associated equipment.
- e) none of the above

17) DDD defines:

- a) a unique number assigned to the distributor of the product.
- b) a unique number assigned to the manufacturer of the product.
- c) the product number.
- d) none of the above

18) E defines:

- a) the license type code.
- b) the radionuclide group.
- c) the principal use code.
- d) whether the product is a source or device.
- e) none of the above

- 19) A source has been registered and according to its registration certificate has a leak test frequency of 6 months. Can a device that uses this source be approved for a leak test frequency greater than 6 months?
- a) Yes b) No
- 20) A vendor located in an Agreement State wants to distribute a device to persons generally licensed under 10 CFR 31.5 or AS equivalent. Who would perform the safety evaluation?
- a) NRC
b) CRCPD
c) Agreement State regulatory authority
d) none of the above
- 21) A person located in a non-Agreement State requests to distribute a device that contains both cesium-137 (byproduct material) and cobalt-57 (NARM). Who would perform the safety evaluation?
- a) NRC would perform the review of the cesium-137 device.
b) The State Health Department for which the distributor resides would perform the review for the cobalt-57 device.
c) The State Health Department for which the distributor resides would perform both device reviews.
d) CRCPD would perform the reviews.
e) NRC would perform both reviews.
f) none of the above
- 22) A person located in Illinois would like to manufacture and distribute a product for custom use by the U.S. Army at one of their facilities in Maryland. Who would register the product?
- a) Illinois would issue the registration certificate for the product.
b) Maryland would issue the registration certificate for the product with the facility in Maryland listed as the custom user.
c) NRC would issue the registration certificate for the product with the facility in Maryland listed as the custom user.
d) none of the above
- 23) A quality control/quality assurance plan would include checks to ensure that:
- a) the product was manufactured and assembled in accordance with the descriptions and drawings (including dimensions, materials, tolerances) submitted in support of the application.
b) all safety features related to radiation safety operate properly.
c) radiation levels are within maximum level stated in the application.
d) none of the above.

- 24) An applicant submits an application for a safety evaluation of a sealed source to be used in a real-time computerized tomography device. The device is designed to measure high pressure and high temperature steam pipe wall thicknesses in electric utility plants during operation. Your co-worker is on leave and you are asked to complete the evaluation. You note that your co-worker has reviewed and approved the entire application with the exception of prototype testing. The applicant has enclosed approximately 18 pages of test procedures and results which demonstrate that the source can be classified as special form. You determined that the source has met the special form test requirements. Do you accept these tests and conclude that the source has been prototype-tested adequately?
- a) Yes b) No
- 25) An applicant used a helium pressurization test to demonstrate that the source was not leaking radioactive material. The applicant states that they followed the procedures outlined in ANSI/HPS N43.6-1997, Section A.2.2.6. Upon further review of the applicant's application, you notice a note on their drawing of the source assembly. The note refers them to a document that contains assembly procedures. The procedures state that the radioactive isotope source is to be melted and poured into the capsule leaving no void spaces. A plug is to be placed over the capsule to prevent any movement of the radioactive material and welded in place. Do you accept the applicant's claim that the source did not leak?
- a) Yes b) No

PART II: Licensing Questions

Choose all answers that apply, unless specifically directed otherwise.

- 1) The applicant has requested approval of a device containing 100 millicuries of americium-241 designed to measure the thickness of the adrenal gland in humans. In addition to your safety evaluation, which approval needs to be granted before a certificate can be issued?
- a) 410k
b) 510k
c) Form 313
d) distribution license
e) none of the above
- 2) You receive an application for a safety evaluation of an industrial gauging device from a manufacturing firm located in Germany. Does the applicant have to establish a USA address?
- a) Yes b) No

- 3) An iridium-192 sealed source used in industrial radiography (not in storage) will only be approved for a leak test interval of:
- a) 3 months
 - b) 12 months
 - c) 36 months
 - d) 6 months
 - e) none of the above
- 4) You are asked to review a safety evaluation of a 12 inch long, 1 inch in diameter irradiator source. Which requirement(s) apply to irradiator sources that are to be used in a category IV irradiator.
- a) doubly encapsulated
 - b) radioactive material must be non-dispersible as practical and insoluble
 - c) source must be made of stainless steel or equivalent local corrosion resistant material
 - d) must be subject to a bend test
 - e) must pass appropriate test for temperature, impact, pressure, vibration, and puncture
 - f) source isotope must be cobalt-60 or cesium-137

PART III: Radiation Protection

Choose all answers that apply, unless specifically directed otherwise.

- 1) You receive a phone call from a manufacturer preparing an application for safety evaluation of a gauging device to be used in the petrochemical industry under a specific license. The applicant wants to know the maximum acceptable surface radiation levels for the device. You tell the applicant that an acceptable level is:
- a) 50 mr/hr
 - b) 2 mr/hr
 - c) 100 mr/hr
 - d) 200 mr/hr
 - e) no regulatory limit
 - f) none of the above
- 2) The manufacturer measured the external radiation levels at a distance 5 cm from the device. The maximum reading was 5 mr/hr when the device contained a point source containing 100 mCi of Cesium-137. What would you approximate the radiation level to be at 1 meter from the device.
- a) 0.25 mr/hr
 - b) 0.025 mSv/hr
 - c) 0.0125 μ r/hr
 - d) 0.125 μ Sv/hr
 - e) none of the above

- 3) A manufacturer calculated the following external radiation levels for a strontium-90 source.

<u>Distance from surface</u>	<u>Radiation level</u>
5 cm	2.0 mr/hr
30 cm	0.056 mr/hr
100 cm	5.0 μ r/hr

Would you accept the data?

- a) Yes b) No

- 4) You are asked to review a safety evaluation for a device intended for distribution to general licensees. The applicant submitted information on conditions of use and the expected yearly dose that a person using the device would receive. In order to approve this device, the total effective dose needs to be below:

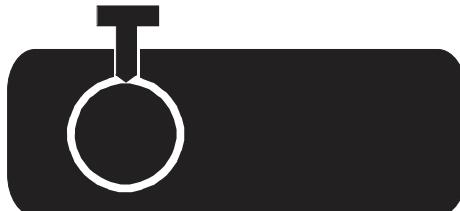
- a) 4 rem
- b) 100 millirem
- c) 500 millirem
- d) 2 millirem
- e) 200 millirem
- f) none of the above

PART IV: General Engineering Principles

Choose all answers that apply, unless specifically directed otherwise.



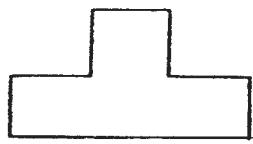
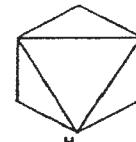
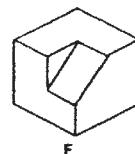
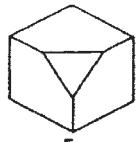
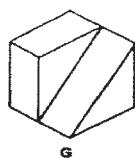
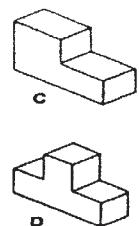
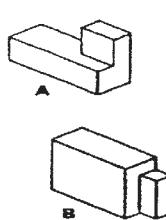
- 1) The diagram above depicts a source capsule that is:
 - a) doubly encapsulated
 - b) singly encapsulated
 - c) triply encapsulated
 - d) none of the above
- 2) From the metals listed below, in general, which metal has the best corrosion resistance?
 - a) carbon steel
 - b) stainless steel
 - c) wrought iron
- 3) An applicant proposes to place a source capsule in a holder and use a bolt to hold the source in place (see the figure below).



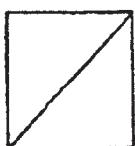
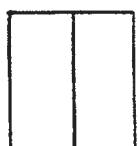
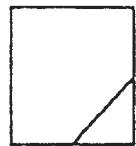
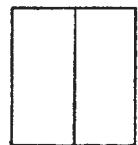
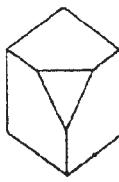
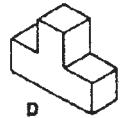
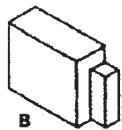
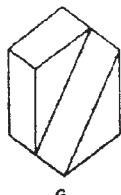
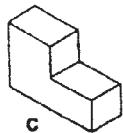
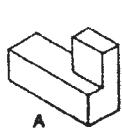
For this type of attachment method, you should consider which of the following?

- a) bolt strength and shape
- b) the amount of threads in contact with the source holder
- c) vibration
- d) wall thickness of source
- e) torque specification for installation of the bolt
- f) none of the above

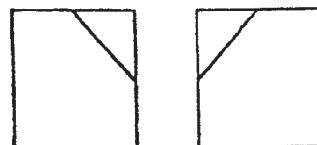
For questions 4-7, three views of an object will be provided, the top drawing is the top of the object, the bottom left drawing is the front view and the bottom right drawing is the right side of the object. For each question, match the three views with the correct object.



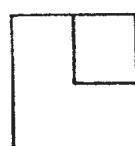
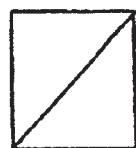
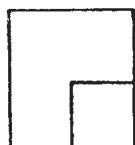
For questions 8-11, three views of an object will be provided, the top drawing is the top of the object, the bottom left drawing the front view and the bottom right drawing is the right side of the object. For each question, match the three views with the correct object.



8)



9)

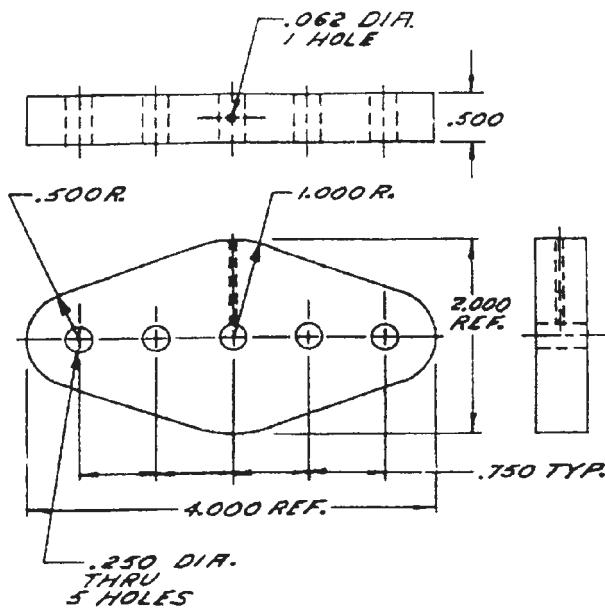


10)



11)

For questions 12-17, refer to the drawing below.



12) The overall dimensions of the part are:

- a) $5.0 \times 2 \times 2$
- b) $4.0 \times 2 \times 0.5$
- c) $4.0 \times 0.5 \times 0.5$

13) Do all the holes go all the way through the full width/thickness of the part?

- a) Yes
- b) No

14) What does R. define?

- a) round
- b) radius
- c) reamed hole
- d) reference

15) How many holes are there?

- a) 5
- b) 13
- c) 6

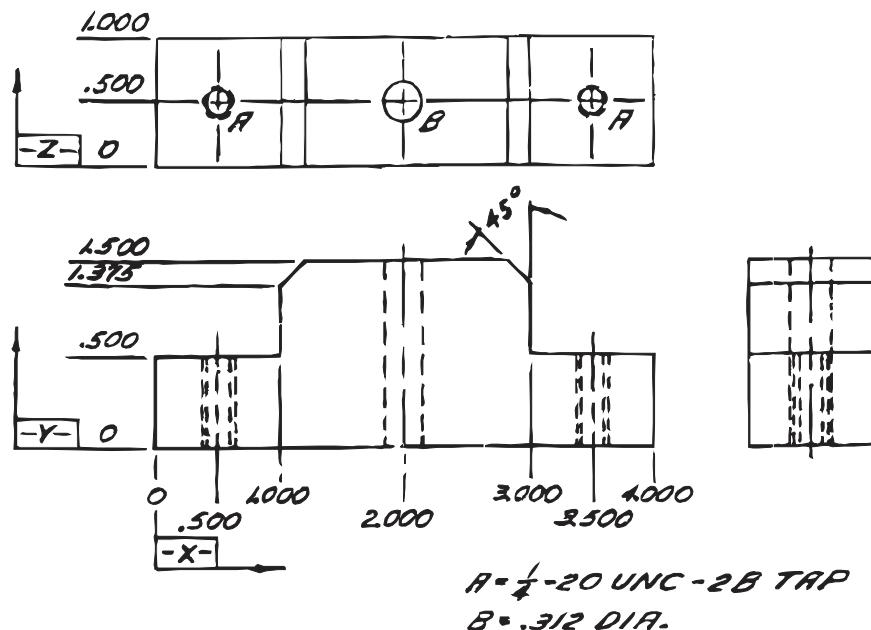
16) What is the length of the 0.062 diameter hole?

- a) 0.5
- b) 0.750
- c) 1.000
- d) 0.875

17) What is the distance from the left end of the part to the center of the first hole?

- a) 0.250
- b) 0.500
- c) 0.750
- d) 0.375

For questions 18-21, refer to the drawing below.



- 18) What is the height of the 45° chamfer?
 - a) 0.125
 - b) 1.5
 - c) 1.375
 - d) 0.375
 - e) 0.500

- 19) What is the distance between the centers of the two holes marked A?
 - a) 1.500
 - b) 3.000
 - c) 3.500

- 20) What is the distance from the center of the hole marked A to the edge of the part?
 - a) 1.000
 - b) 0.250
 - c) 0.500

- 21) What do the double dotted lines of hole A signify?
 - a) clearance hole
 - b) sleeve insert
 - c) tapped hole

- 22) Can years of use of a product without any known failures, either when used by a custom user or used in another country, ever be accepted in lieu of prototype testing of the product?
- a) Yes b) No
- 23) You are reviewing a safety evaluation for a new type of brachytherapy source (needle source). The manufacturer claims their product is superior to others on the market because of the size and flexibility of the wire. The source wire is made of a composite material that has a tensile strength of 300 psi. It has a 1/8 inch diameter and an eyelet on one end of the needle. The manufacturer stated that the sources passed the prototype tests as outlined in ANSI N44.1-1973. This standard specifies a prototype tensile stress test. The test requires a mass of 11 kg (5 lbs.) be suspended from the eyelet end of needle for at least 60 seconds. Do you accept the applicant's statement that the source passed the prototype tests? (hint: tensile strength - force/area, see Appendix C ANSI/HPS N43.6-1997)
- a) Yes b) No
- 24) A person wants to register a product designed for use under a general license. The product is described as a small, bench-top device intended to be used in research and development laboratories to measure densities of chemical samples. The device does not have a shutter since access to the radiation is restricted by the design of the device. The applicant claims that no prototype testing of the device was performed since the device will be used in controlled laboratory environments. At a minimum, which of the following prototype test(s) should be performed on the device?
- a) elevated temperature test
b) vibration test
c) drop test
d) calibration/performance test of the device (reading versus actual sample density)
e) pressure test
f) none of the above
- 25) An applicant submits the results of prototype testing of a portable device that has an internal shutter mechanism. The device was equipped with a source having nominal activity and was surveyed prior to testing. You have reviewed and accepted the procedures and results for all testing except for the drop test. A drop test was performed with the shutter locked in the closed position. At the conclusion of this test, the shutter mechanism could not be operated due to internal damage, however, the shutter remained closed. The applicant claims the device passed the drop test since the shutter remained closed. What should your conclusion be?
- a) You can accept the test
b) You need to verify that the applicant surveyed the device at the conclusion of the test and found that the radiation levels were within acceptable limits.
c) You need to verify that the applicant performed a leak test to ensure there was no loss of containment of the radioactive material.
d) You cannot accept the results without further explanation and testing.
e) none of the above

- 26) Should industrial gauges be equipped so that they can have the shutter locked in the open and closed positions?
- a) Yes b) No
- 27) An industrial gauging device is subjected to a drop test (simulating falling from its mounting) and a vibration test (simulating extreme vibration it may experience from the process line) to simulate accident conditions. Both tests are performed with the shutter in the open position. Which of the following are acceptable results?
- a) After the drop test, the shutter remained in the open position. However, the operator was able to return the shutter to the closed position by normal means.
- b) After the drop test, the shutter remained in the open position due to the handle bending. However, the operator was able to return the shutter to the closed position by removal of the handle.
- c) As a result of subjecting the device to extreme vibration, power to the shutter mechanism was lost and the shutter returned to the closed position due to the automatic spring return system.
- d) After the drop test, the shutter returned to the closed position. However, the fixed shielding moved, causing the radiation levels around the device to increase.
- e) none of the above
- 28) You are reviewing an application for a gauge that is designed to be used outdoors to measure sludge as it is pumped to a waste recycling plant. The applicant requests that the device be intended for specific licensees since he wants them to be able to replace their own sources. The drawings indicate that the device does not have a shutter mechanism, is not hermetically sealed, and that source is to be held in the shield solely by a strong adhesive. Upon review of the operations manual, you note, under a section entitled, "Source Replacement", it states, "To remove the source use water to dissolve the adhesive holding the source in the shutter." How would you proceed?
- a) approve the device for licensing purposes
- b) request technical specification for the adhesive
- c) cannot approve the device as currently designed
- d) none of the above
- 29) An applicant has submitted an application for approval of a beta source to be used in industrial applications. The source is thin-walled to allow better attenuation. The source is 1/4 inch in diameter and 5 inches long. You have completed your review and found everything acceptable except that the application did not address labeling of the source. You called the applicant and he proposed that he would engrave the source with the manufacturer's logo, the model number and serial number. The applicant stated that he would send you the specifics on how the source was to be labeled. Based on the above, how should you proceed?
- a) approve the source design
- b) review label content and, if adequate, approve the source design
- c) review label content and impact the engraving may have on the integrity of the source
- d) none of the above

2003 SS&D Workshop - Pre-test Answer Sheet

Directions: mark out the correct answer, or answers, completely.

Example: right

wrong

a

Part I: General SS&D Questions

- 1) a b c d
2) a b c d e
3) a b c d e f
4) a b c d
5) a b c d e
6) a b c d e
7) a b c d

Part II: Licensing Questions

- 1) a b c d e
2) a b
3) a b c d e
4) a b c d e f

Part III: Radiation Protection

- 1) a b c d e f
2) a b c d e
3) a b
4) a b c d e f
5) a b c d e f g h
6) a b c d e f g h
7) a b c d e f g h
8) a b c d e f g h
9) a b c d e f g h
10) a b c d e f g h
11) a b c d e f g h
12) a b c d e f g h
13) a b c d e f g h
14) a b c d e f g h
15) a b c d e f g h
16) a b c d e f g h
17) a b c d e f g h
18) a b c d e f g h
19) a b c
20) a b c d
21) a b c d e f
22) a b c d
23) a b c d
24) a b
25) a b

Part IV: General Engineering Principles

- 1) a b c d
2) a b c
3) a b c
4) a b c d e f g h
5) a b c d e f g h
6) a b c d e f g h
7) a b c d e f g h
8) a b c d e f g h
9) a b c d e f g h
10) a b c d e f g h
11) a b c d e f g h
12) a b c
13) a b
14) a b c d
15) a b c
16) a b c d
17) a b c d
18) a b c d e
19) a b c
20) a b c
21) a b c
22) a b
23) a b
24) a b c d e f
25) a b c d e
26) a b
27) a b c d e
28) a b c d
29) a b c d

2003 SS&D Workshop - Pre-test Answer Sheet

CORRECTLY MARKED ANSWER SHEET

Part I: General SS&D Questions

- 1) a c d
2) b c e
3) a c d e f
4) b c d
5) a b d e
6) a b c d
7) a _____
8) b c
9) b c d
10) a c d e f
11) _____ e f
12) _____ e
13) _____ c _____ f
14) a b d
15) b c d
16) a b c e
17) a b d
18) b c d e
19) b
20) a b d
21) a b c d f
22) a b d
23) _____ d
24) a
25) a

Part II: Licensing Questions

- 1) a c d e
2) b
3) a b c e
4) _____ d f

Part III: Radiation Protection

- 1) a b c d f
2) a b c e
3) a
4) a b d e f
5) a c d e f g h
6) a b d e f g h
7) b c d e f g h
8) a b c d e f g h
9) a b c d f g h
10) a b c d e g h
11) a b c d e f g h
12) a b c d e f g h
13) a b c d e f g h
14) a b c d e f g h
15) a b c d e f g h
16) a b c d e f g h
17) a c d
18) b c d e
19) a c
20) a b
21) a b
22) b
23) a
24) a _____ d e f
25) a _____ e
26) a
27) b d e
28) a b d
29) a b d

Part IV: General Engineering Principles

2003 SS&D Workshop - Pre-test Answer Sheet

ANSWER LOCATION SHEET

Part I: General SS&D Questions

- 1) Performing the Review
- 2) Prototype Testing
- 3) Prototype Testing
- 4) Prototype Testing
- 5) Prototype Testing
- 6) Prototype Testing
- 7) Writing the Certificate
- 8) QA/QC
- 9) Writing the Certificate
- 10) Writing the Certificate
- 11) Servicing & User Inst.
- 12) Design (etc.)
- 13) Design (etc.)
- 14) Writing the Certificate
- 15) Writing the Certificate
- 16) Writing the Certificate
- 17) Writing the Certificate
- 18) Writing the Certificate
- 19) Servicing & User Inst.
- 20) Performing the Review
- 21) Performing the Review
- 22) Performing the Review
- 23) QA/QC
- 24) Prototype Testing
- 25) Prototype Testing

Part II: Licensing Questions

- 1) Performing the Review
- 2) Writing the Certificate
- 3) Servicing & User Inst. **and**
Design (etc.)
- 4) Design (etc.)

Part III: Radiation Protection

- 1) Radiation Profiles
 - 2) Radiation Profiles
 - 3) Radiation Profiles
 - 4) Radiation Profiles
-
- Part IV: General Engineering Principles**
- 1) Blueprint Reading
 - 2) General Engineering Principles
 - 3) General Engineering Principles (cont.)
 - 4) Blueprint Reading
 - 5) Blueprint Reading
 - 6) Blueprint Reading
 - 7) Blueprint Reading
 - 8) Blueprint Reading
 - 9) Blueprint Reading
 - 10) Blueprint Reading
 - 11) Blueprint Reading
 - 12) Blueprint Reading
 - 13) Blueprint Reading
 - 14) Blueprint Reading
 - 15) Blueprint Reading
 - 16) Blueprint Reading
 - 17) Blueprint Reading
 - 18) Blueprint Reading
 - 19) Blueprint Reading
 - 20) Blueprint Reading
 - 21) Blueprint Reading
 - 22) Prototype Testing
 - 23) General Engineering Principles
 - 24) Prototype Testing
 - 25) Prototype Testing
 - 26) Design (etc.)
 - 27) Prototype Testing
 - 28) Design (etc.)
 - 29) Prototype Testing