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SELF-STUDY TEST

Radiobiology and Radiation Protection

Questions are taken from the *Nuclear Medicine Self-Study Program I*, published by The Society of Nuclear Medicine

DIRECTIONS

The following items consist of a heading followed by lettered options related to that heading. Select the one lettered option that is best for each item. Answers may be found on page 1477.

For each source of radiation exposure to the U.S. population (items 1–5), select the most correct estimate of the magnitude of annual exposure dose by comparison with natural background radiation (answers A–E).

A. background exposure (BE)
B. 50% BE
C. 15% BE
D. 5% BE
E. 1% BE

1. diagnostic x-ray
2. nuclear medicine procedures
3. nuclear power
4. consumer products
5. fallout from weapons testing

For each type of acute effect caused by whole-body radiation exposure in humans (items 6–9), select the *lowest* radiation dose (*A–E*) that could be expected to elicit the effect.

A. 50 rads
B. 200 rads
C. 350 rads
D. 1250 rads
E. 5000 rads

6. the prodromal syndrome
7. lethality
8. the LD_{50}
9. seizures and coma

For each of the radiation-related responsibilities listed (items 10–13), select the appropriate advisory group or federal agency (*A–E*).

A. Nuclear Regulatory Commission (NRC)
B. Food and Drug Administration (FDA)
C. Environmental Protection Agency (EPA)
D. National Council on Radiation Protection and Measurements (NCRP)
E. Center for Devices and Radiological Health (CDRH)

10. Responsible for deciding whether a new radiopharmaceutical should be approved for use in humans
11. Establishes radiation protection standards for use in clinical nuclear medicine
12. The lead agency for the U.S. government for the establishment of federal radiation protection policy
13. Regulates the use of radioactive materials for research in humans under the auspices of the Radioactive Drug Research Committee (RDRC)

ICRP Publication 26 recommends a number of significant changes in the radiation protection guidelines that concern nuclear medicine. These recommendations form the basis of proposed changes in Part 20 of Title 10 of the Code of Federal Regulations. Which of the following are recommendations of ICRP Publication 26?

14. Adoption of a de minimis dose level of 1 mrem for occupational exposure
15. Elimination of 5(N – 18) formula for calculating permissible lifetime doses
16. Abandonment of the critical organ concept in favor of a weighted total body dose equivalent that takes into account irradiation of all radiosensitive organs and tissues
17. Addition of doses received from internally deposited radionuclides to those from external irradiation in determining the total effective dose equivalent

The decision to administer potassium iodide (KI) to populations after a nuclear reactor accident is based on

18. the expectation that thyroid doses in the exposed population will exceed 500 mrems.

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19. a balancing of ^{131}I hazard vs. risk of ^{127}I.
20. federal regulations for emergency situations.

Patients are rushed to the emergency room of your hospital after an accident at a nuclear reactor site. Concerning the care of patients potentially contaminated with radionuclides,

21. the JCAHO requires all accredited hospitals to have written plans for the care of such casualties.
22. steps must be taken immediately to interrupt any radiation-induced injury process.
23. the patient, even if critically injured, should be kept in the ambulance until a radiation survey can be completed.
24. the patient should be washed and showered prior to treatment to remove as much contamination as possible.
25. a determination of the absolute lymphocyte count is essential.

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ITEM 1-5: Sources of Radiation Exposure
ANSWERS: 1, A; 2, C; 3, E; 4, D; 5, D
The sources of radiation dose received by the U.S. population have been summarized by a number of national and international bodies. The estimates vary slightly between agencies, but the estimates given below from the National Academy of Sciences, BEIR Committee (1980), represent an average of these values.

U.S. General Population Exposure Estimates

Source	Average Individual Dose (mrem/year)	%	Ratio of Source$_i$: Natural Background
Natural background	82	44	1:1
Medical x-rays, 79 mrem/year radiopharmaceuticals, 14 mrem/year	93	50	1:1
Fallout	4–5	2.4	1:20
Consumer products	3–4	1.9	1:20
Nuclear industry	<1	<0.5	1:80
Airline travel	0.6	0.3	1:130
Total	≅185	≅100	

Note added in proof: Recently, the NCRP has reevaluated radiation exposure in the U.S. (NCRP Report No. 93, *Ionizing Radiation Exposure of the Population of the United States.* 1987.) This new assessment of the average exposure of the members of the U.S. population to all sources of ionizing radiation is the first based upon a common unit, the effective dose equivalent (which weighs the risks of partial-body irradiation). The average annual effective dose equivalent to individuals in the U.S. population is 360 mrem (3.6 mSv). The major part of this, 300 mrem (3 mSv), is from background which includes 200 mrem (2 mSv) from radon and its decay products. The relative contribution of medical diagnosis, which amounts to 54 mrem (39 mrem from x-ray examinations and 14 mrem from radiopharmaceuticals), is less than that estimated in previous evaluations. This contribution, 15% of the total, is less than the 50% estimate of BEIR-1980 (93 mrem medical versus 185 mrem total).

ITEMS 6-9: Acute Radiation Syndromes
ANSWERS: 6, A; 7, B; 8, C; 9, E
About 2 hours after rapid exposure of all or a major portion of the body to high doses of radiation, humans begin to show signs and symptoms of acute gastrointestinal and neuromuscular effects, which are collectively called the prodromal syndrome. Its German designation *Strahlenkater* is compounded from "radiation" and "hangover," which its symptoms mimic. Nausea and vomiting begin at about 50 rads. The threshold for radiation-induced lethality in humans is about 200 rads. As dose levels rise above this, mortality increases. Humans appear to develop and recover from signs of hematologic damage more slowly than other mammals. The peak incidence of human deaths from hematologic damage occurs at about 30 days but deaths continue for up to 60 days, whereas the peak incidence of death in animals occurs at 10–15 days. Thus the lethal dose for 50% of an irradiated population, the LD_{50}, is best estimated for a period of 60 days in humans and 30 days in animals. The estimated $LD_{50/60}$ for humans is 350 rads. Seizure and coma occur only after total body doses on the order of 5000 rads.

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ITEM 10-13: Federal Radiation Advisory and Regulatory Agencies

ANSWERS: 10, B; 11, A; 12, C; 13, B

The Nuclear Regulatory Commission (NRC) is charged by Congress with the responsibility for the regulation of the uses of source material (natural uranium and thorium), special nuclear material (enriched uranium and plutonium), and by-product material (fission products and materials that are created by fission–neutron transmutations). The NRC does not regulate naturally occurring (such as radium, radon, and potassium-40) and accelerator-produced radioactive materials (NARM). To assure the safe use of by-product materials, the NRC publishes regulations that establish minimum training and experience requirements for licensure to use by-product materials and radiation protection standards that must be observed by licensees. Many of these regulations apply directly to the clinical practice of nuclear medicine. The regulations published by the NRC carry the full weight of law, and violation of the regulations or license conditions may result in civil penalties and suspension or revocation of the license. Most states have established radiation protection regulations and licensing procedures similar to those of the NRC for the safe use of NARM. Many states have signed formal agreements with the NRC to assume the responsibility for regulation of by-product material uses within their own borders and, thus, license all radioactive materials, whether by-product or NARM; such states are called Agreement States.

The Food and Drug Administration is charged by Congress with assuring the safety and efficacy of drugs used in the United States. During those years that the Atomic Energy Commission (AEC) was responsible for the licensing of by-product material, FDA deferred to the judgement of AEC in determining which radiopharmaceuticals should be licensed to physicians for general use. The FDA assumed responsibility for the premarketing evaluation and approval of radiopharmaceuticals some years ago and now subjects radiopharmaceuticals to the same regulatory approval process as applies to all other types of drugs.

Occasions may arise wherein a researcher would like to use an unapproved radioactive drug to investigate a very well-defined question in a limited population of research subjects, e.g., to establish pharmacokinetics of a particular drug in a rare disease. The Radioactive Drug Research Committee (RDRC) regulations were established by the FDA to deal with these special circumstances. Where applicable, these regulations facilitate research with particular radioactive drugs because they obviate submission of a "Notice of Claimed Investigational Exemption for a New Drug" (IND). After an institution has established an FDA-approved RDRC, the committee is authorized to review and approve research studies of the type defined by the RDRC regulations; further approval of the research protocol by the FDA is not required. The RDRC regulations are quite specific as to what types of investigation are permitted, and prescribe organ and whole-body dose limits, as well.

The Environmental Protection Agency (EPA) is charged by Congress with the responsibility for ensuring that the environment is not harmed by the actions of industry, government, or private citizens. The dividing line between EPA and NRC responsibilities with regard to radiation hazards has always been fuzzy, and in many cases NRC licensees must deal with both agencies in trying to resolve differences between regulations established by each agency. The EPA has been assigned the lead agency responsibility for establishment of broad radiation protection policies for federal agencies, a role formerly filled by the now-defunct Federal Radiation Council. For example, the International Commission on Radiation Protection (ICRP) recently recommended a new approach to radiation protection standards. The EPA was responsible for determining whether the United States should adopt the new ICRP approach. The EPA is also the lead agency in attempting to solve the radioactive waste disposal problem.

The National Council on Radiation Protection and Measurements (NCRP) was chartered by Congress as a nonprofit organization in 1964. The NCRP is an advisory group of eminent radiation scientists who develop recommendations on how to deal with specific radiation protection questions. These recommendations are published as NCRP reports. NCRP reports are strictly advisory, but the imprimatur of the NCRP makes them de facto national standards of good radiation protection practice. In the absence of specific regulations from NRC or other federal agencies, most health physicists implement NCRP recommendations as an integral part of their radiation protection programs.

The Center for Devices and Radiological Health (CDRH) is a branch of the FDA that develops performance standards for medical devices and for applications of radiation in humans. The CDRH also develops educational programs designed to enhance user and community awareness of proper ways to use radioactive materials and radiation-emitting machines. Performance standards established by CDRH are published as FDA regulations in Title 21 of the Code of Federal Regulations.

ITEMS 14-17: ICRP Publication 26

ANSWERS: 14, F; 15, T; 16, T; 17, T

ICRP Publication 26 reflects the results of a complete restudy of the radiobiologic literature and a fresh look at radiation protection guidelines. ICRP 26 recommends that occupational exposure limits be based on control of annual exposure without considering separately the pattern of exposure over the working lifetime of the individual. Thus, ICRP recommends that the 5(N – 18) formula for calculating acceptable lifetime dose be eliminated. ICRP 26 further recommends that the critical organ concept be abandoned in favor of assessment of the total radiation insult to the body. The absorbed dose to each organ within the body is to be calculated, and then appropriate weighting factors for each organ are applied to arrive at the total effective dose-equivalent. There probably will be further refinement in the numerical values of the weighting factors, but the general concept seems to be firmly established. Finally, ICRP 26 closed a long-standing loophole regarding the dose contribution from internally deposited radionuclides. Previous guidance from ICRP and still-current regulations of the U.S. Nuclear Regulatory Commission provide dose limits for irradiation by sources external to the body and require that the activity of any internally deposited radionuclides be assessed and recorded, but included no requirement that the absorbed dose due to the internally deposited radionuclides be included in the 5 rems/year

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(0.05 Sv/year) limit. ICRP 26 recommends that both internal and external doses be included in dose estimates. Although this seems a straightforward requirement, internal dosimetry is still more an art than a science, and there is substantial controversy within the health physics community about how the internal dose should be handled in the case of long-lived radionuclides that also have long biological half-lives.

The de minimis concept was included in the proposed revisions to Part 20 of Title 10, Code of Federal Regulations, but there was no discussion of a numerical definition of de minimis occupational exposure in ICRP 26.

ITEMS 18-20: Thyroid Blocking of Populations

ANSWERS: 18, F; 19, T; 20, F

After the accident at Chernobyl in April 1986, the Russian authorities administered KI to many persons (thought to be 100,000). In the U.S., there is no national stockpile of KI and few states have emergency stores of KI. Guidelines for administration of KI to members of the general public have been developed by the FDA, the NCRP, and the American Thyroid Association. Each has come up with different projected "action" thresholds, i.e., the expected thyroidal doses at which general population "blocking" should be considered; these range from 5–25 rems to up to 100 rems anticipated doses to the thyroid.

In the event of an accident, it is the relevant local health authority that has the responsibility for making recommendations to its population, although the FDA and the Federal Emergency Management Agency (FEMA) would play supporting roles in the decision and distribution process. As in any other health question, the problem is one of balancing the benefits of diminished radiation dose to the thyroid if KI is administered early (ideally, before or within a few hours after significant environmental contamination by radioiodine) versus the probability of allergic or other adverse pharmacologic responses to KI. Because the radiation induction of thyroid cancer, on the one hand, and allergic events on the other are both rare events, the decision is not easy, and the public perception of risk needs to be taken into account.

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ITEMS 21-25: Medical Management of Patients Contaminated with Radionuclides

ANSWERS: 21, T; 22, F; 23, F; 24, F; 25, T

Although accidents involving radiation injury are rare events, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has required, since February 1978, that all hospitals have a procedure for handling these emergencies. The Joint Commission's *Accreditation Manual for Hospitals* states:

> *The hospital shall have written plans for the timely care of casualties arising from both external and internal disasters, and shall document the rehearsal of these plans.*

Rarely are injuries due to ionizing radiation life threatening, either to the victim or to the treating staff. The effects of these injuries became manifest over a period of time (as a function of dose, dose rate, and portion of the body irradiated) and, except for agents to block organ uptake (iodide) or to remove internally deposited radionuclides (chelators), there is no treatment that can interrupt this injury process.

When the ambulance arrives, the driver and other personnel should remain with the vehicle until they have been monitored for contamination. Information as to the nature of the accident, the type of contamination, and any prior attempts at decontamination should be obtained from those who accompany the patient. The patient's airway, breathing, and circulation should be checked immediately. If critically injured, the patient should be taken directly to the radiation emergency area of the emergency room with attention to avoidance of gross contamination of the emergency room. When the injuries are not critical or life-threatening, the patient should be surveyed in or near the ambulance. Contaminated clothing should be removed near the vehicle, tagged, and retained for a later survey.

The external contamination by beta and gamma emitters should be measured over the whole body. Next, one should determine if wounds are contaminated by direct measurements over them. In addition, swab samples of the body orifices should be taken, always *before* the patient is washed and showered. If internal contamination is suspected, all urine, feces, vomitus, and wound secretions should be collected for radioassay. Surgical clothing (i.e., scrub suits, gowns, mask, and 2 pairs of gloves) and waterproof shoe covers are reasonable protective measures for medical personnel. Those using decontamination liquids should wear waterproof aprons as well.

To establish a baseline for evidence of radiation injury, a complete blood count, including platelets and white cell differential count, should be performed immediately; counts should be repeated at 12- to 24-hr intervals if indicated by the rate of change in the absolute lymphocyte count. The determination of the absolute lymphocyte count is *essential,* because circulating lymphocytes are extremely radiosensitive and the decline in their numbers furnishes the earliest and most accurate indication of radiation injury.

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Note: For further in-depth information, please refer to the syllabus pages included at the beginning of *Nuclear Medicine Self-Study Program I: Part I.*