Lesson 9: FDA PAGs and Ingestion Pathway Protective Actions

Lesson Overview

The purpose of this lesson is to provide an overview of FDA Protective Action Guides (PAGs).

- Upon completion of this lesson, you will be able to:
- Describe the role, responsibilities, and response capabilities of the United States Department of Agriculture (USDA) in the intermediate phase of a nuclear power plant accident.
- Define the ingestion pathway zone.
- Describe the measures recommended by USDA to be taken by food producers, processors, and transporters to prevent the contamination of foodstuffs and to protect the public from ingestion of contaminated agricultural products.
- Define derived intervention level (DIL) and describe the process of applying DILs.

Remember you can access the glossary in one of two ways throughout this course. You can select the glossary button in the top right hand corner of each main content screen. In addition, on content screens you can select underlined words to access their definitions in the online glossary. Selecting an underlined word will take you directly to its definition in the glossary.

This lesson should take approximately **1 hour** to complete.

FDA Protective Action Guides (PAGs)

On August 13, 1998, the U.S Food and Drug Administration (FDA) issued a guidance document entitled Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. The FDA has a responsibility for issuing guidance on planning actions for evaluating and preventing contamination of human food or animal feeds and on the control and use of these products should they become contaminated.

To facilitate implementation of the FDA PAGs during an incident, the National Response Framework (NRF) has assigned the United States Department of Agriculture (USDA) the responsibility for providing assistance to state and local governments in developing agricultural protective action recommendations and in providing agricultural damage assessments. You will learn more about USDA's role later in this lesson.

The FEMA REP Program Manual, April 2012 also provides guidance on implementation of the FDA PAGs.

FDA PAG Values

The FDA PAGs are:

- 5 mSv (0.5 rem) for committed effective dose equivalent (CEDE); or
- 50 mSv (5 rem) for committed dose equivalent (CDE) to an individual tissue or organ, whichever is the more limiting

The current nominal estimate for the general population for lifetime total cancer mortality for low-LET (linear energy transfer) ionizing radiation, delivered at low doses and low dose rates, is approximately 1 in 200 for a reference dose equivalent in the whole body of 100 mSv (10 rem). For 5 mSv (0.5 rem) CEDE, the associated lifetime cancer mortality would be 2.25 x 10-4 or approximately 1 in 5000.

For comparison, the estimate of the normal total cancer mortality rate in the United States for the general population, not associated with additional radiation doses from ingestion of contaminated food from an accident, is 1.9x10-1 or approximately 1 in 5. For example, in a general population of 10,000 individuals, each receiving a dose of 5 mSv (0.5 rem) CEDE, the number of cancer deaths in that population of individuals could increase, in theory, by about 2 cancer deaths over the lifetimes of the individuals—that is, from the expected number of 1900 to 1902.

FDA PAG Recommendations

For a nuclear power plant incident, the foundation planning requirement document, the updated NUREG-0654 states the following in criteria J.9. "Each State and local government shall establish a capability to implement protective measures based on protective action guides and other criteria."

It further states in part, "This shall be consistent with the recommendations of…with those of DHEW (HHS)/FDA regarding radioactive contamination of human food and animal feeds…" Alternative approaches may be used if such approaches satisfy the applicable statute, regulations, or both.

The recommendations advise that health risk to the public should be averted by limiting the radiation dose received as a result of consumption of accidentally contaminated food. This should be accomplished by:

- Setting derived intervention levels (DILs) on the radionuclide activity concentration permitted in human food.
- Taking protective actions to reduce the amount of contamination.

You will learn about derived intervention levels (DILs) later in this lesson. Next, you will learn more about protective actions.

Preventive Protective Actions (1 of 2)

Preventive protective actions are actions taken to prevent or reduce contamination of water, milk and food products. Protective actions should be initiated subject to evaluation of the situation and should continue until, in the absence of the actions, the concentrations remain below the DILs. Protective actions can be taken to:

- Avoid or limit, through precautionary measures, the amount of contamination that could become incorporated in human food and animal feeds.
- Delay or limit consumption of human food and animal feeds suspected of being contaminated until the concentration of contamination has been determined.
- Reduce the amount of contamination in human food and animal feeds.

Precautionary actions should be implemented to avoid placing in jeopardy persons implementing the actions. For example, in the case of an accident involving a commercial nuclear power plant, if the predictions of the magnitude of future off-site contamination are persuasive, precautionary actions might need to be taken and completed prior to declaration of a general emergency (GE).

The FDA guidance does not provide limits on concentrations that should be permitted in animal feeds. However, protective actions for animal feeds are included as measures to reduce or prevent subsequent contamination of human food.

Preventive Protective Actions (2 of 2)

Sample analysis will be required to quantify contamination.

- **Milk**
  - Remove lactating animals from pasture and place in shelter. Use feed from enclosed silos, granaries, or barns
  - Withhold contaminated milk from market
  - Store for prolonged periods of time to allow for radioactive decay. Fluid milk may be kept for long periods of time using ultra-high-temperature pasteurization
  - Divert fluid milk. Milk may be used for manufactured milk products such as cheese, butter, and dried milk
- **Fruits and Vegetables**
  - Cover exposed products, when possible
  - Remove surface contamination by washing and peeling
  - Preserve fruits and vegetables by canning, freezing or dehydration
- **Meat and Meat Products**
  - Place animals on uncontaminated feed and water and place in shelter
- **Poultry and Poultry Products**
  - Poultry being raised indoors are probably not contaminated
  - Free-range poultry should be placed on uncontaminated feed and water and placed in shelter
- **Soils**
  - Idle or dispose
  - Alternate crops (substitute other crops that contribute little or no contamination to the human diet, such as cotton)
  - Plow deeply (radioactive contamination is moved well below the root levels of crops to prevent uptake)
  - Lime (limits root uptake)
- **Grains**
  - Mill and polish to remove hulls
  - Allow to weather (remain in the field where some natural decay will occur)
  - Store separately from previously harvested grain
- **Water**
  - Cover open wells, rain barrels and tanks

- Disconnect filler pipes from runoff supplies
- Close water intake valves from contaminated sources

- **Fish and Marine Life**
  - Close the fishing season. This includes lakes, rivers, and ponds (public and private)
  - Prevent harvesting of seafood
- **Honey**
  - Stop collection of honey
  - Stop cross-pollination
- **Game and Wildlife**
  - Close hunting season
- **Additional Considerations**
  - Notify food processors, distributors and farmers
  - Initiate quarantine and/or embargo procedures
    - Develop food control area to isolate contaminated products
    - Develop food control points to prevent transfer of contaminated products from one area to another
  - Develop sampling strategy plan for intermediate and long term
    - Sampling must be done often and repetitively
    - Provide appropriate laboratory support
    - Decide if farmers can reenter contaminated area as radiation workers
    - Obtain Federal assistance
    - Consider insurance and indemnification issues
    - Develop recovery plan, including reentry, relocation and return

USDA Response Role

As you learned earlier in this lesson, USDA is responsible for facilitating implementation of the FDA PAGs during an incident. In the next section of this lesson, you will learn more about USDA's specific role.

The USDA's major concern is food safety. In response to a radiological emergency, the USDA's Food Safety and Inspection Service assumes the lead USDA agency role.

The principal USDA role is to provide guidance and assistance to state and local governments. USDA advisors will assist state and local officials, in coordination with the Department of Health and Human Services (HHS) and the EPA, in recommending and implementing of agricultural protective actions to limit or prevent the ingestion of contaminated food.

The USDA will provide assistance to assess damage to crops, soil, livestock, poultry, and processing facilities from radiological contamination. It will incorporate findings into a damage assessment report.

USDA National Response Framework (NRF) Responsibilities

Under the National Response Framework (NRF), the USDA is responsible for:

- Inspection of meat and meat products, poultry and poultry products, and egg products identified for interstate and foreign commerce to ensure that they are safe for human consumption.
- Assistance in monitoring the production, processing, storage, and distribution of food through the wholesale level to eliminate contaminated products or to reduce the contamination in the products to a safe level.
- Collection of agricultural samples within the ingestion pathway zone.
- Assistance in the evaluation and assessment of data to determine the impact of the emergency on agriculture.

Advisory Team for Environment, Food, and Health

USDA personnel, along with EPA, HHS, and other Federal agencies as needed, will serve on the Advisory Team for Environment, Food, and Health. The Advisory Team will convene for SAE incidents and above. This team will provide a mechanism for timely interagency coordination of advice and recommendations to the state agency and lead federal agency (LFA) concerning:

- Environmental assessments (field monitoring)
- PAGs and their application to the emergency
- Data and assessment from the Federal Radiological Monitoring and Assessment Center (FRMAC)
- Preventing or minimizing the contamination of milk, food, and water and exposure through ingestion
- Disposition of contaminated livestock and poultry
- Minimizing losses of agricultural resources from radiation effects
- Availability of food, animal feed and water supply inspection programs to ensure wholesomeness
- Relocation, reentry and other radiation protection measures prior to recovery
- Recovery, return, and cleanup issues
- Health and safety advice or information for the public and for workers
- Estimates of effects of radioactive releases on human health and environment
- The use of radioprotective substances (e.g., thyroid blocking agents), including dosage and projected radiation doses that warrant the use of such drugs
- Other matters, as requested by the Coordinating Agency

The Federal Radiological Monitoring and Assessment Center (FRMAC)

The Advisory Team is usually collocated with the Federal Radiological Monitoring and Assessment Center, or FRMAC. For emergencies with potential for causing widespread radiological contamination where no on-scene FRMAC is established, the functions of the Advisory Team may be accomplished in the coordinating agency response facility in Washington, DC.

The Advisory Team will not release information or make recommendations to the public unless authorized to do so by the coordinating agency.

Other USDA personnel will also assist DOE/EPA at the FRMAC with:

- Information on current harvesting to set sampling priorities.
- Collection of agricultural samples.

Ingestion Pathway Zone

Now that you have learned about the FDA PAGs, you will learn about how contamination occurs through the ingestion exposure pathways.

The ingestion pathway zone is the area approximately within a 50 mile radius of a nuclear power plant. In the ingestion pathway zone, radionuclides may be deposited on crops, vegetation, bodies of surface water, and ground surfaces. The resulting contaminated food and water may present a risk to the public and to livestock.

Potential Ingestion Pathways

There are three ingestion pathways.

- Food - Four potential pathways have been identified by which radionuclides released during an accident may contaminate food supplies:
    - Direct deposition on edible plants
    - Deposition via contaminated irrigation water
    - Uptake by plants from soil
    - Deposition on edible plants by resuspension of radionuclides deposited on soil
- Water - The pathways resulting in contamination of potable water supplies are:
    - Airborne plume deposition on surface water
    - Runoff from soil or snow contaminated by plume
    - Leaching and/or migration of radioactive fluids to water supplies
    - Direct release of contaminated effluents to a river or other water body that supplies drinking or irrigation water
- Milk - One pathway has been identified that results in contamination of the milk supply: airborne plume deposition on pasture, ingestion of contaminated feed by cow, and concentration of radionuclides in milk. Although radionuclides such as Cs-134, Cs-137, Sr-89 and Sr-90 may result in doses through the milk pathway, the I-131 dose will probably be larger than that of each of the other nuclides.

Derived Intervention Levels (DILs) (1 of 2)

Earlier in this lesson, you learned that protective actions should be initiated and continue until concentrations of contamination are below the Derived Intervention Levels (DILs). You will now learn about why they are established and how they are calculated.

DILs are limits on the concentrations of radionuclides permitted in human food distributed in commerce. DILs are also recommended for non-commercial products. They are established to

prevent consumption of undesirable amounts of radionuclides and are expressed in units of radionuclide activity per kilogram of food, i.e., Becquerel per kilogram (Bq/kg).

Although the basic PAG recommendations are given in terms of projected dose equivalent, it is often more convenient to use specific radionuclide concentrations as the basis for protective actions.

Derived Intervention Levels (DILs) (2 of 2)

A DIL is the concentration of a radionuclide in food that would lead to an individual's receiving a dose equal to the PAG. DILs establish limits on the radionuclide activity permitted in human food.

DILs are calculated in becquerels per kilogram and are derived by dividing the intervention level of dose by the product of the fraction of food assumed to be contaminated, the quantity of food consumed, and the dose received per unit of activity.

The FDA DILs provide a large margin of safety for the public because each DIL is set according to a conservative scenario for the most vulnerable group of individuals. In addition, protective actions would be taken if radionuclide concentrations were to reach or exceed a DIL at any point in time, even though such concentrations would need to be sustained throughout the relevant extended period of time for the radiation dose to actually reach the PAG.

DIL = PAG / [(f) (food intake) (DC)]

- DIL = Derived Intervention Level, Bq/kg
- PAG = Protective Action Guide, mSv
- f = Fraction of food assumed contaminated
- Food Intake = Quantity of food consumed, kg
- DC = Dose received per unit of activity, mSv/Bq

DIL Applicability (1 of 2)

Accident types for which DILs were developed:

- **Nuclear Reactors -** The results of food monitoring by the FDA and others following the Chernobyl accident support the conclusion that I-131, Cs-134, and Cs-137 are the principal radionuclides that contribute to radiation dose by ingestion following a nuclear reactor accident, but that Ru-103 and Ru-106 also should be included in considerations. The use of DILs was shown to be a practical way to control the radiation dose from ingestion of food that has been contaminated as a result of a nuclear reactor accident.
- **Nuclear Fuel Reprocessing Plants -** Nuclides of concern from a fuel reprocessing plant accident resulting in contamination of the environment include: Sr-90, Cs-137, Pu-239, and Am-241. Plutonium and Americium are alpha emitters.
- **Nuclear Waste Storage Facilities -** Sr-90, Cs-137, Pu-239, and Am-241 are also of concern at nuclear waste storage facilities.

- **Nuclear Weapons -** Without nuclear detonation, Pu-239 is the only nuclide released during this type of accident. Pu-239 half-life is 2.411×10^4 years.
- **Radioisotope Thermoelectric Generators and Radioisotope Heater Units Used in Space Vehicles -** Pu-238 decay provides power for many spacecraft.
- **All Other Contamination -** In unique circumstances, such as transportation accidents, other radionuclides may contribute radiation doses through the food ingestion pathway. These situations are not specifically addressed in the FDA recommendations. An evaluation of the radiation dose from ingestion of these other radionuclides should be performed, however, to determine if the PAGs would be exceeded. The FDA guidance provides guidance for these "minor isotopes".

DILs apply during the first year after an accident. If there is concern that food will continue to be significantly contaminated beyond the first year, the long-term circumstances need to be evaluated to determine whether the DILs should be continued or if other guidance may be more applicable.

DIL Applicability (2 of 2)

Food with concentrations below the DILs is permitted to move in commerce without restrictions. Food with concentrations at or above the DILs is not normally permitted into commerce. However, state and local officials have flexibility in deciding whether or not to apply restrictions in special circumstances, such as permitting use of food by a population group with a unique dependency on certain food types.

Recommended DILs (1 of 2)

Each DIL applies to the sum of the concentrations of the radionuclides in the group at the time of measurement, rounded up to two significant figures.

Note: Divide Ru-103 by 6800 and divide Ru-106 by 450. If the sum is less than or equal to 1, the food is edible; if the sum is greater than 1, the food is inedible.

The PAG of 5 mSv (0.5 rem) CEDE is most limiting for Cs-134 + Cs-137 and Ru-103 + Ru-106. The PAG of 50 mSv (5 rem) CDE to a single specific tissue or organ is most limiting for Sr-90, I-131, and Pu-238 + Pu-239 + Am-241.

Recommended DILs (2 of 2)

The recommended DILs for each radionuclide group are applicable to foods as prepared for consumption. For dried or concentrated products such as powdered milk or concentrated juices, adjust by a factor appropriate to reconstitution, and assume the reconstitution water is not contaminated. For spices, which are consumed in very small quantities, use a dilution factor of 10.

Now that you have learned about the recommended DILs, you will learn about the assumptions upon which these recommendations were based.

DIL Assumptions: Age Groups

The DILs were calculated for six age groups using protective action guides, dose coefficients, and dietary intakes, including tap water for drinking, relevant to each radionuclide and age group. The age groups included:

- 3 months
- 1 year
- 5 years
- 10 years
- 15 years and adult (>17 years)

Protection of the more vulnerable segments of the population and the practicality of implementation were major considerations in the selection of DILs. These considerations led to the selection of a single DIL for each radionuclide group based on the most limiting PAG and age group for the radionuclide group.

There are different DILs for infant and adult because the different body weights and organ sizes as well as the percentage of total dietary intake of a particular food will influence the severity of the dose received.

DIL Assumptions: Fractions Assumed to be Contaminated

The DIL calculations presume that contamination will occur in 30% of the dietary intake. The value of 30% was chosen based on the expectation that normally less than 10% of the annual dietary intake of most members of the population would consist of contaminated food.

An additional factor of three was applied to account for limited subpopulations that might be more dependent on local food supplies.

An exception was made for I-131 in the diets of the three-month and one-year age groups, where the entire intake over a 60-day period was assumed to be contaminated (because the diet for these age groups consists of a high percentage of milk).

Therefore, f = 0.3, except for I-131 in infants, where f = 1.0.

DIL Assumptions: Food Intake

Food intake includes all dietary components for each age group, including tap water used for drinking, and is the overall quantity consumed in one year.

There are exceptions in the period of time for I-131 and Ru-103 due to the more rapid decay of these radionuclides.

- I-131: 60 days since its half-life is 8.04 days
- Ru-103: 280 days since its half-life is 39.3 days

Dietary intakes were derived from EPA and USDA data.

DIL Assumptions: Dose Coefficients

The dose coefficients used, in mSv/Bq, were taken from ICRP Publication 56 (ICRP 1989). The most limiting dose from each of the nine radionuclides per age group was used in the calculation to arrive at the DIL. Ru-103 and Ru-106 are chemically identical; however, their widely differing half-lives (39.3 days and 373 days, respectively) result in markedly differing individual DILs that do not permit simple averaging.

Example: Calculating the DIL for Cs-134 and Cs-137:

$$\text{DIL (Bq/kg)} = \frac{\text{PAG(mSv)}}{\text{(f)x (food intake in kg)x (dose coefficient in}\frac{\text{mSv}}{\text{Bq}}\text{)}}$$

where:

- f = 0.3 for all except I-131
- Food intake = 943 kg (largest annual intake of all age groups was adult),
- Dose coefficient = 1.9×10^{-5} for Cs-134, 1.3×10^{-5} for Cs-137 (for adults since they had the largest dietary intake)
- PAG = 5 mSv CEDE (most limiting PAG for Cs group)

$$\text{DIL (Bq/kg)} = \frac{5\ \text{mSv}}{(0.3)\text{x}\ (943\ \text{kg})\text{x}\ (1.9\ \text{x}\ 10^{-5}\ \frac{\text{mSv}}{\text{Bq}})} = 930\ \text{Bq/kg (Cs – 134)}$$

$$= \frac{5\ \text{mSv}}{(0.3)\text{x}\ (943\ \text{kg})\text{x}\ (1.3\ \text{x}\ 10^{-5}\ \frac{\text{mSv}}{\text{Bq}})} = 1360\ \text{Bq/kg (Cs – 137)}$$

930 + 1360 = 2290 / 2 = 1145 ≈ 1200 Bq/kg DIL (Cs group)

The answer should be rounded up to two significant figures, according to the PAG.

Implementation of Protective Actions

Now that you've learned about how DILs are established and how they guide protective actions, you will learn about protective actions that should be implemented before and after laboratory results arrive that confirm food contamination.

- **Prior to receiving laboratory results -** Protective actions that can be taken within an area likely to be affected before confirmation of contamination via laboratory results include:
    - Simple precautionary actions to avoid or reduce the potential for contamination of food and animal feeds prior to arrival of the contamination

- Temporary embargoes to prevent the introduction into commerce of food that is likely to be contaminated. This action is appropriate only if there is significant expectation that contamination has occurred.

Protective actions can be taken before the release or arrival of contamination if there is advance knowledge that radionuclides may accidentally contaminate the environment. Simple precautionary actions include modest adjustment of normal operations before arrival of contamination. These will not guarantee that contamination in food will be below the DILs, but they will significantly reduce the severity of the problem.

Distribution and use of possibly contaminated food and animal feed is halted until the situation can be evaluated and monitoring and control actions instituted. Temporary embargoes are employed when the concentrations are not yet known. Because there is potential for negative impact on the community, justification for this action must be significant. Any embargo imposed should remain in effect at least until laboratory results are obtained. The geographical area under the embargo would depend on the accident sequence, the meteorological conditions, and the food affected.

- **After receiving laboratory results -** Protective actions that should be implemented when the contamination in the food equals or exceeds the DILs are:
  - Temporary embargoes to prevent the contaminated food from being introduced into commerce
  - Normal food production and processing actions that reduce the amount of contamination in or on food to levels below the DILs

Embargoes should continue until measured concentrations are below the DILs.

Normal food production and processing procedures that could reduce the amount of contamination in or on the food could be simple (e.g., holding to allow for decay, or removal of surface contamination by brushing, washing, or peeling) or could be complex. Blending of contaminated food with uncontaminated food is not permitted by law (adulteration).

Lesson Summary

Let's summarize what you have learned in this lesson:

- Before the arrival of the airborne plume, precautionary protective actions may be instituted to lessen the severity of contamination in milk, food, and water.
- The USDA is responsible for providing assistance to state and local governments in developing agricultural protective action recommendations and providing agricultural damage assessments.
- The ingestion pathway zone is the area approximately within a 50-mile radius of a nuclear power plant.
- Before confirmation of contamination, employment of temporary embargoes will limit the amount of contaminated food placed in commerce.
- DILs are concentrations of radionuclides in food that will cause a PAG to be exceeded.

The next lesson will provide an overview of field monitoring organization and protection.