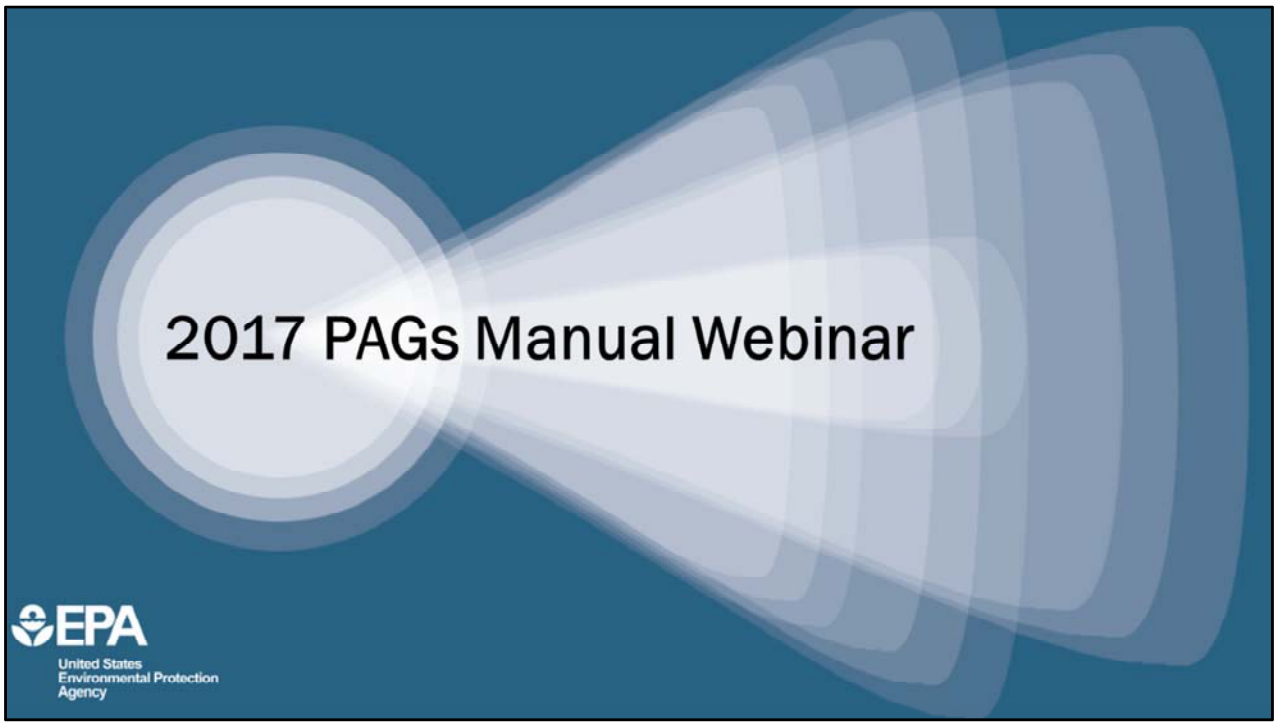
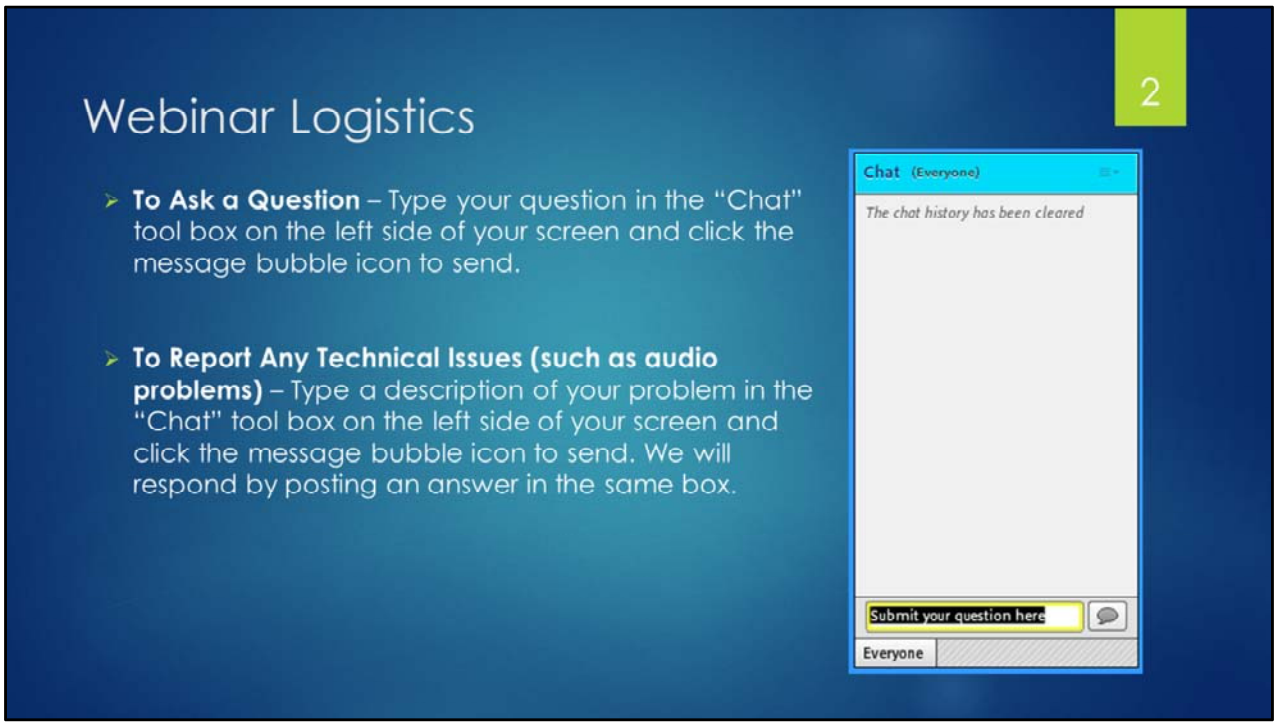


Welcome to the PAG Manual webinar. We have a team of key staff on the line to help monitor for questions, comments and to help out. We'll get right into it after some logistics and housekeeping.

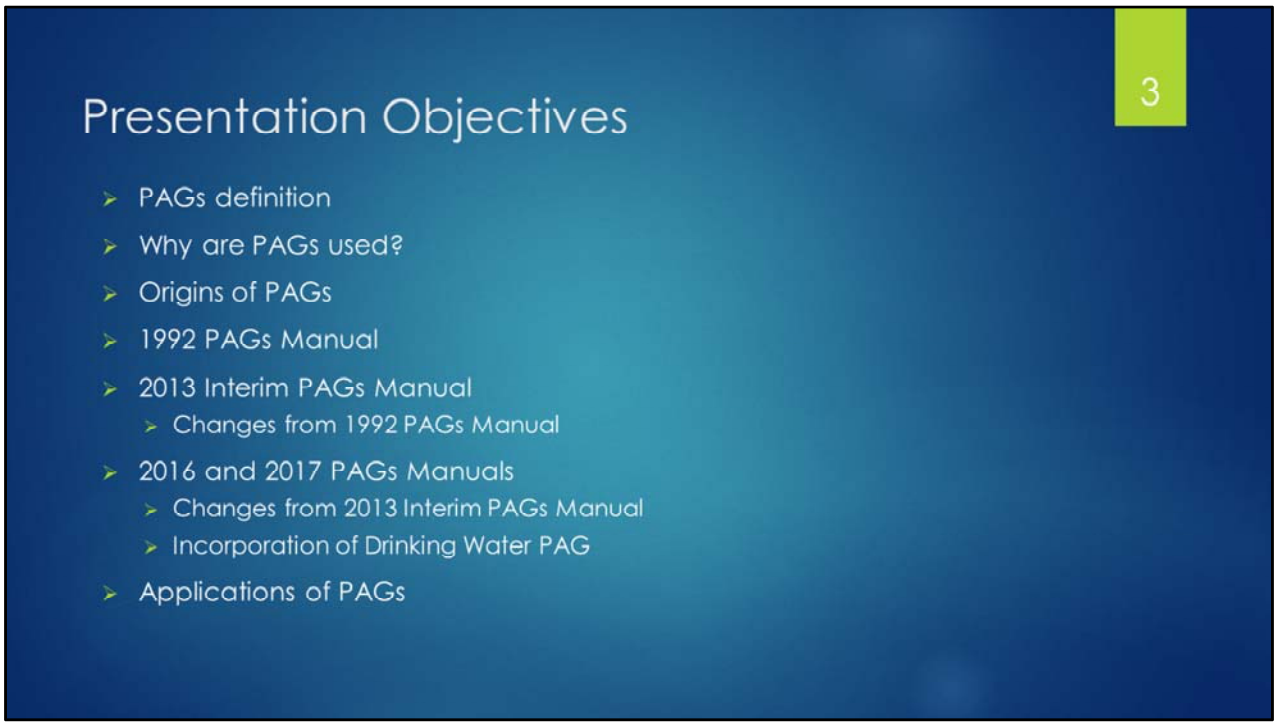


Let's get started by going over a few housekeeping items.

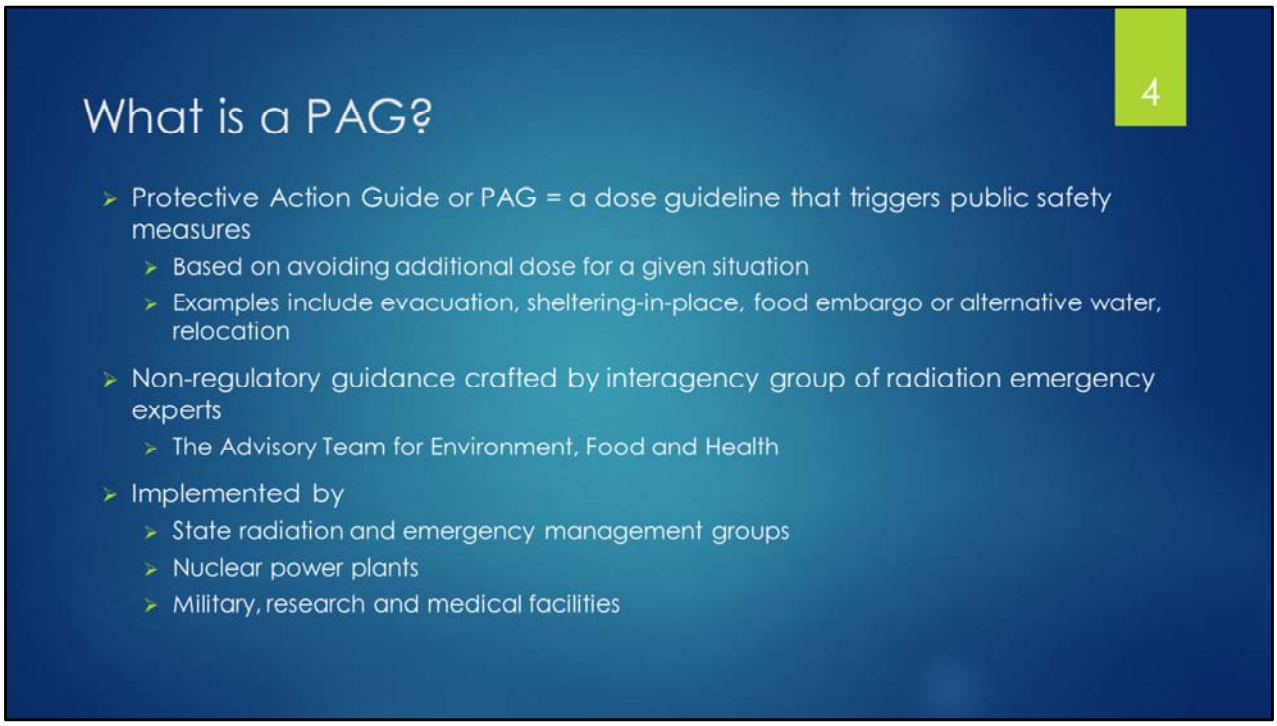
We are using EPA's Adobe Connect service for today's webinar. You should be able to see the presentation on your screen now. We ask that all participants who choose to call into the phone line also mute their computer speakers to avoid an echo. We encourage you to submit your questions early. All questions from today's webinar will be collected and answered. If we are unable to respond to your question during today's live webinar, we will compile your question as well as others and respond to all questions as part of a FAQs.

If you experience any technical difficulties during this webinar, you may type a description of your problem in the "chat" box on the left side of your screen. Make sure to click on the chat icon to submit your question. We will respond to your question in the same "chat" box. Now that we have completed a review of the webinar housekeeping items, I would like to turn the webinar over to Sara.

{OPTIONAL: Some webinars may be recorded.}

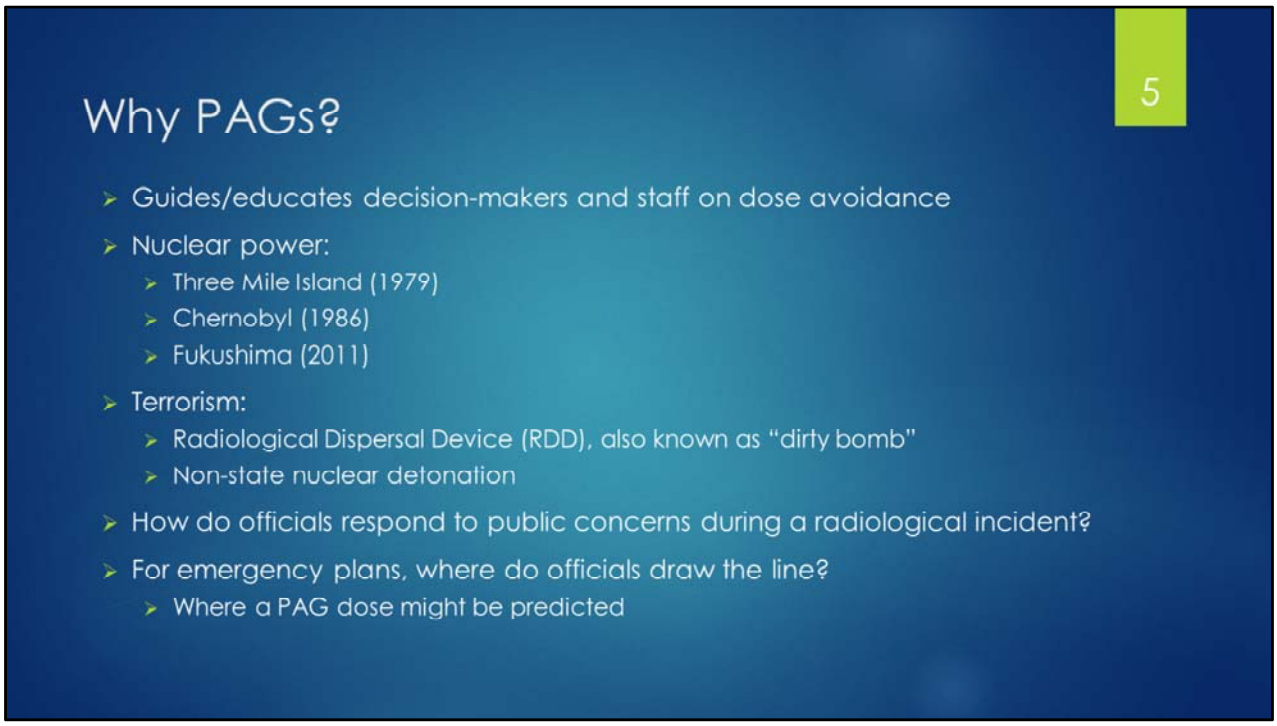


We won't go through the basics of what PAGs are since you are a savvy audience with experience implementing PAGs. Instead we'll run through key points, describe the revisions, and focus on what has changed. During the coming 12 months, your organizations are assessing what changes in plans, procedures, calculations and protocols will need to be made. We've heard from FEMA that rather than taking a hard line on having the new PAGs in place in your plans in precisely 12 months, they'll work with you on the right timing since it's understood that exercise planning and revisions to plans takes time.



EPA publishes the Protective Action Guide (PAG) manual that contains dose guidelines that would trigger public safety measures, such as evacuation or staying indoors, to minimize or prevent radiation exposure during an emergency. It also includes advice on use of pharmaceutical countermeasures, such as potassium iodide (KI), and long-term measures, such as restriction of food, temporary relocation, or permanent resettlement, to avoid or minimize exposure to residual radiation or exposure through the ingestion pathway. Protective Action Guides serve as "health-based tipping points" that assist officials in deciding when it is necessary for people to evacuate, stay inside, issue a food or water advisory, or take other immediate steps to safeguard health during a radiological emergency.

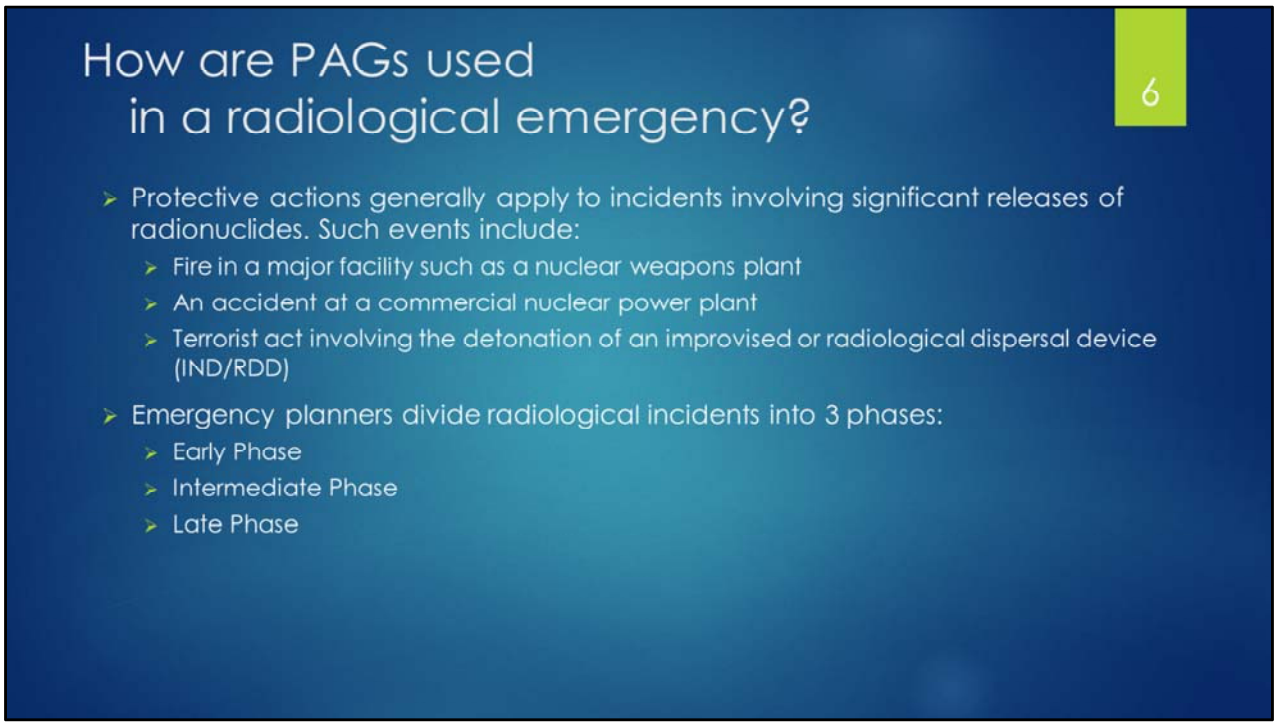
The PAGs provide general guidance to officials, which they can use together with their knowledge of local conditions, to make safety decisions. PAGs have been worked in to all state and many tribal and local emergency plans in some form, and around nuclear power plants, there are Nuclear Regulatory Commission and Federal Emergency Management Agency requirements to use something like PAGs to inform offsite emergency response. States, tribes and localities have the flexibility to make their own plans and PAG levels, too. But the overarching guidance from the federal government has been around since the 1960s, providing localities with consistent, science-based dose levels for protective actions.



The PAG manual was developed to help make timely and effective decisions for dose avoidance by providing background information and relevant guidance under one cover for decision-makers and their supporting staff.

Radiological incidents like Three Mile Island, Chernobyl, and Fukushima all demonstrated important turning points for improvements in preparing and responding to radiological emergencies. Unpredictable events such as a terrorist attack, coupled with unpredictable locations of radiological events make advanced planning challenging. For example, an RDD could detonate anywhere and spread radiological contaminants across a vast range of surfaces and terrain.

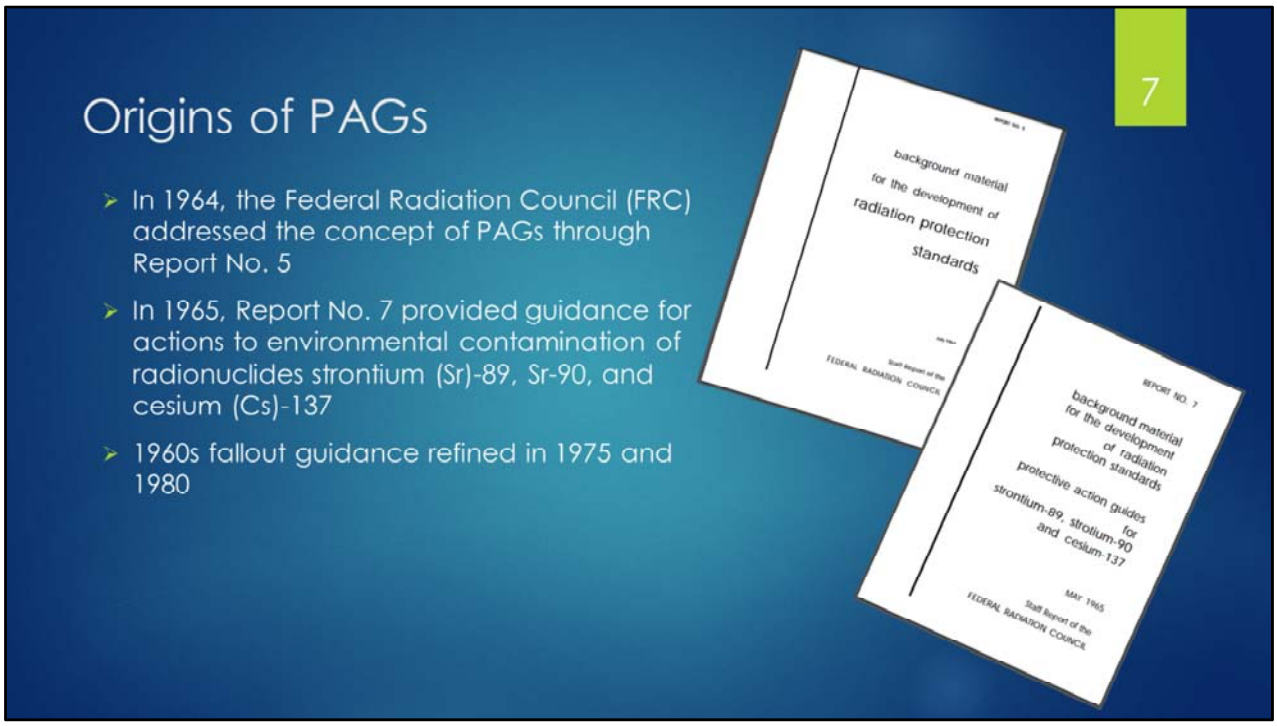
Emergency planners should be prepared to apply PAGs to a wide scope of facilities and circumstances; and to project doses that may trigger the need for protective actions from a release of radioactive material.



In nuclear power plants for instance, emergency action levels can trigger protective actions before any dose might be projected, based on plant conditions. Decision-makers compare estimates of projected doses with the appropriate PAG to determine which actions to take.

Planners divide an incident into Early, Intermediate and Late Phases to apply different PAGs as the emergency response progresses. As more information becomes available, dose tolerance goes down and actions switch to longer term recovery.

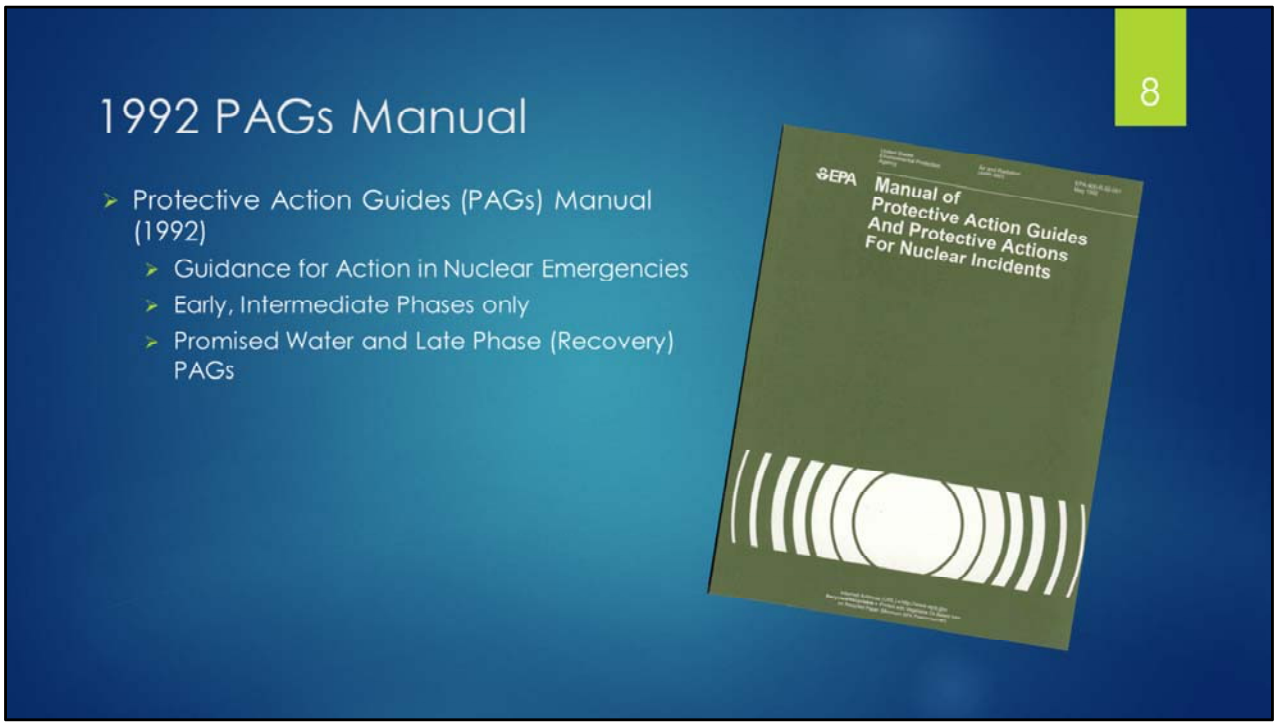
A good resource for discussing how you implement the PAGs is the Advisory Team for Environment, Food and Health (Advisory Team) = Federal interagency group of radiation experts whose mission is to provide radiation safety recommendations to decision-makers at all levels of government following a radioactive release (not directly to the public). The Advisory Team is comprised of radiation expert representatives from FDA, CDC, EPA and USDA.



PAGs have been around a really long time: in the 1960s the Federal Radiation Council developed guidance for federal agencies from fallout and doses at which implementation of protective actions may be appropriate. The council also provided general guidance for the protection of the population against exposure resulting from the accidental release of radioactive materials in the environment– specifically providing a numerical value for an Iodine-131 PAG.

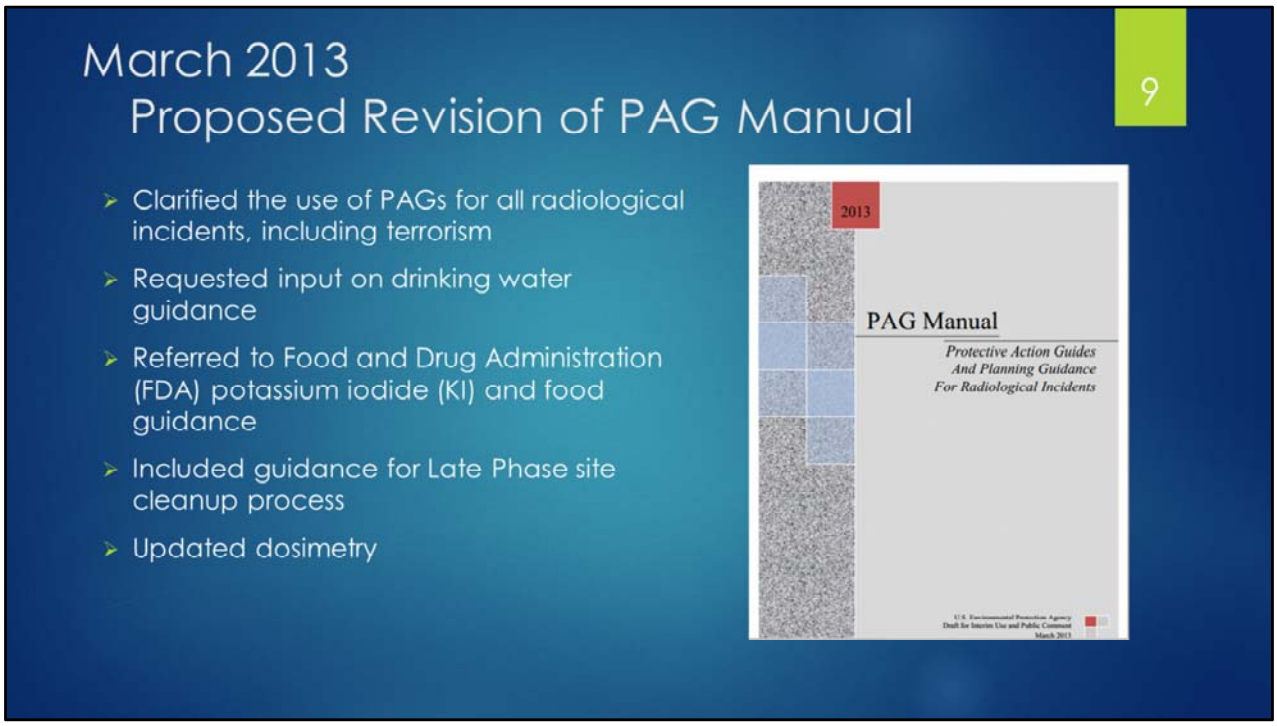
FRC later provided guidance for actions for situations involving contamination of the environment by the radionuclides Sr-89, Sr-90, and Cs-137.

The 1960s fallout guidance was later refined by reports from the NRC in 1975 and 1978, as well as the EPA in PAG Manuals issued in 1975 and 1980 which include planning information and prediction of time frames for releases of radioactive material from potential incidents.



The 1992 PAG manual provided emergency management officials at the federal, state, and local levels with the technical basis to plan responses to radiological emergencies. It was also written to accommodate the "worst release" scenario deemed likely at the time– a major accident at a commercial nuclear power plant (NPP) that would result in significant off-site release of radioactive material.

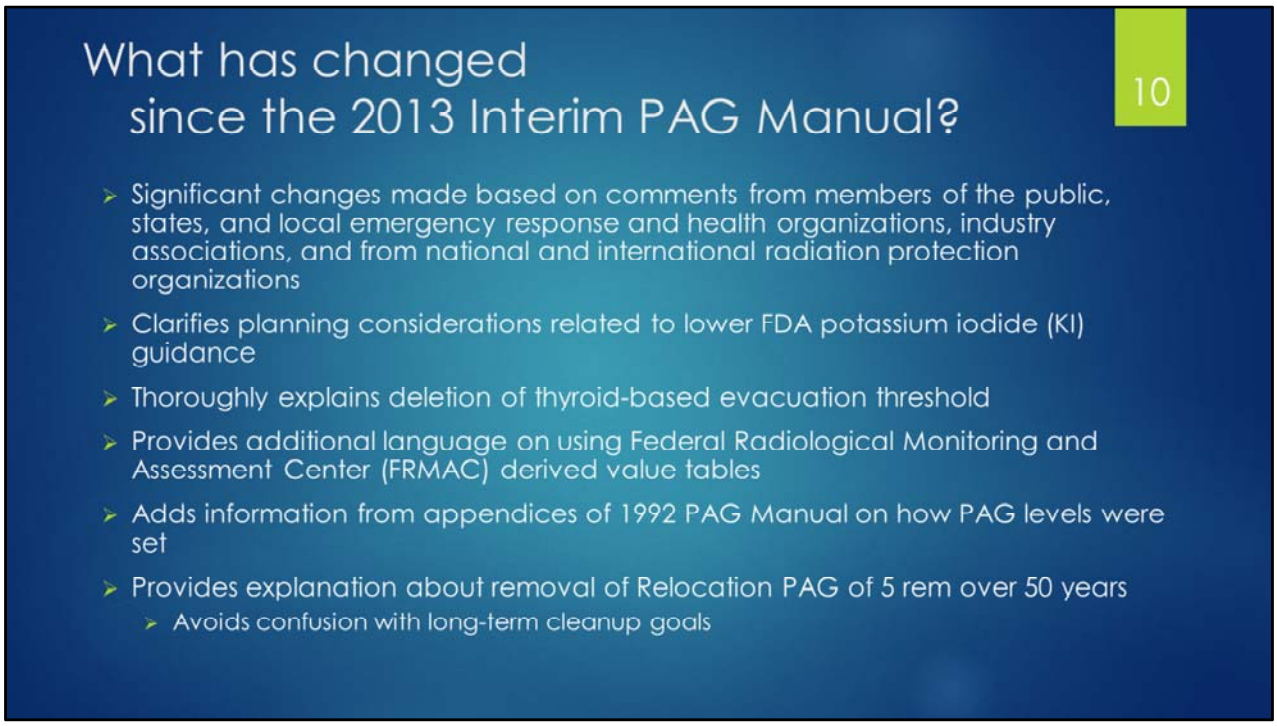
It provided decision-makers with radiation dose-based PAG values for various exposure pathways (e.g. whole body, skin dose, and food ingestion) and associated protective actions adapted to the mix of radionuclides and operational environments associated with commercial NPPs. Early and Intermediate phases are where actions focus on evacuation or sheltering to avoid an airborne plume, or longer term relocation from the most impacted areas. The good news is, there is nothing wrong with this PAG Manual, it's just a bit outdated. It also lacks Late Phase guidance.



The PAGs are authored by an interagency subcommittee of the Federal Radiological Preparedness Coordinating Committee (FRPCC) that EPA chairs. When we issued a revision in 2013 for public comment, significant changes from the 1992 PAG Manual included:

- Applying the PAG Manual to incidents other than just nuclear power plant accidents.
- Referring to current food guidance from the Food and Drug Administration (FDA)
- Providing guidance for potassium iodide (KI) based on the latest FDA guidance.
- Providing basic planning guidance on reentry, clean up and waste disposal.
- Incorporating late phase (cleanup) guidance from the Department of Homeland Security's Radiological Dispersal Device/Improvised Nuclear Device Planning Guidance.

Since the early 1990s, we've made progress in radiation protection so that we now have age- and gender-specific coefficients to calculate radiation doses to people or organs with much better accuracy. Jumping from pencil & paper calculations in an emergency to sophisticated computer codes has enabled great improvements, too. So when we published the proposed update in 2013, we made use of these advances. Drinking water & food in particular are where there are separated PAGs calculations for sensitive age groups, built in to the guidance. Note that we didn't have a drinking water PAG in there, yet.

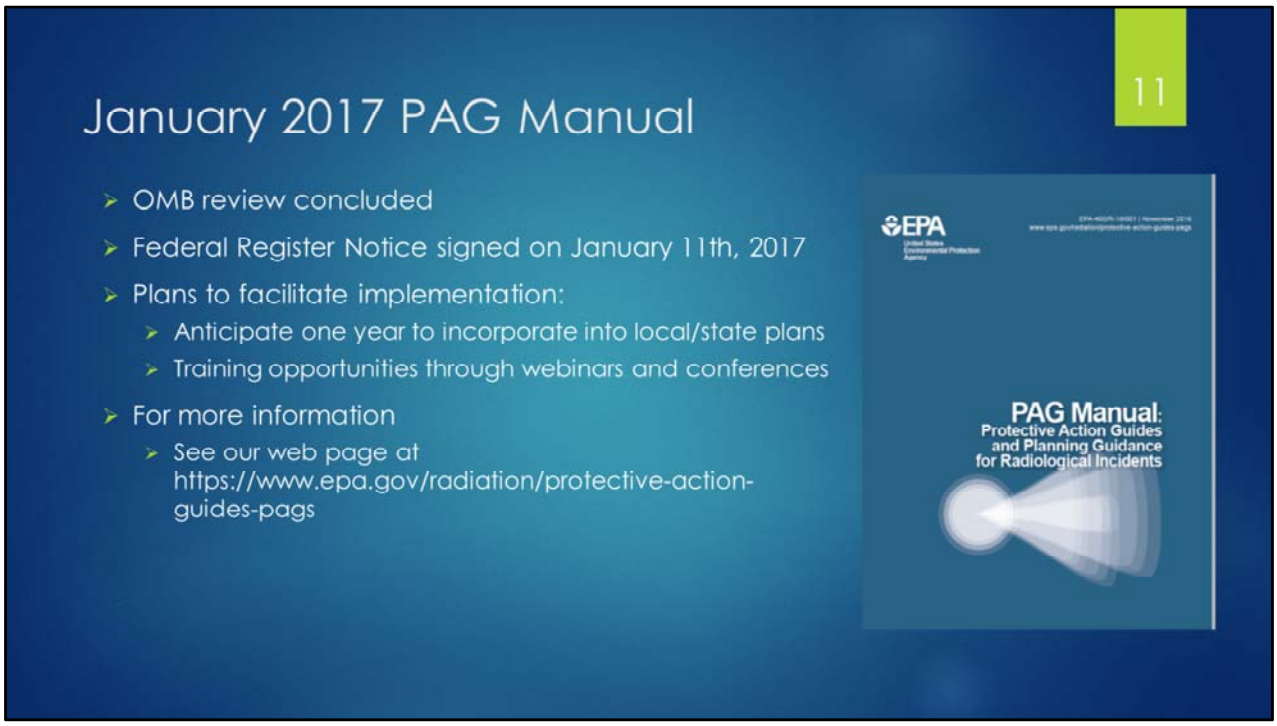


Members of the public, state, and local emergency response and health organizations, industry associations, and from national and international radiation protection organizations provided comments (5,000 of them, thank you) and we used those to make updates in the 2016 PAG Manual. Significant changes were made, based on those comments, including:

- Clarifying planning considerations related to the lower FDA Potassium Iodide (KI) guidance.
- Explaining the deletion of the thyroid-based evacuation threshold more thoroughly.
- Providing additional language on using Federal Radiological Monitoring and Assessment Center (FRMAC) derived value tables.
- Adding information from the appendices of the 1992 PAG Manual on how the PAG levels were set
- Providing explanation about the removal of the Relocation PAG of 5 rem over 50 years to avoid confusion with long-term cleanup goals.
- Planning guidance has been provided for reentry, late phase cleanup, and waste disposal.

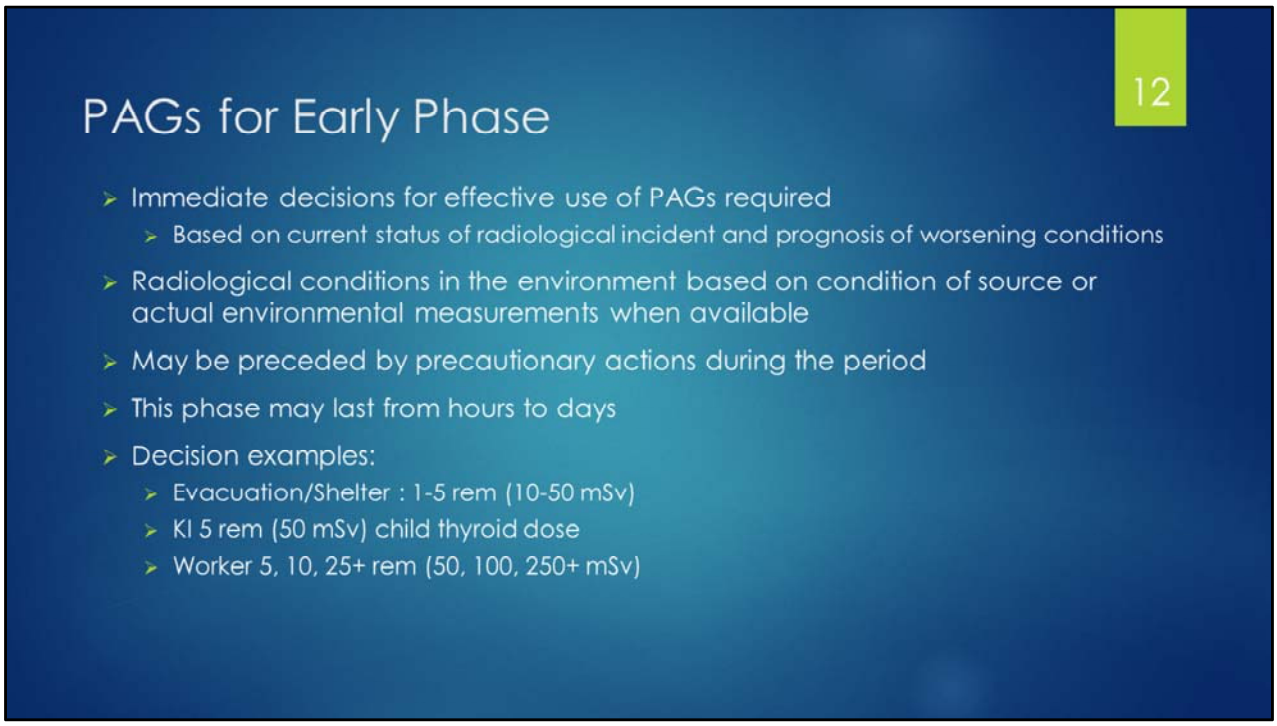
Some things can't be solved by PAGs, for instance, How do you define "clean" or "safe"? The 2016 PAGs (and previous PAGs) are not a line between "clean/unclean" or

“safe/unsafe”, but rather “if/when” to take action during a radiological emergency.



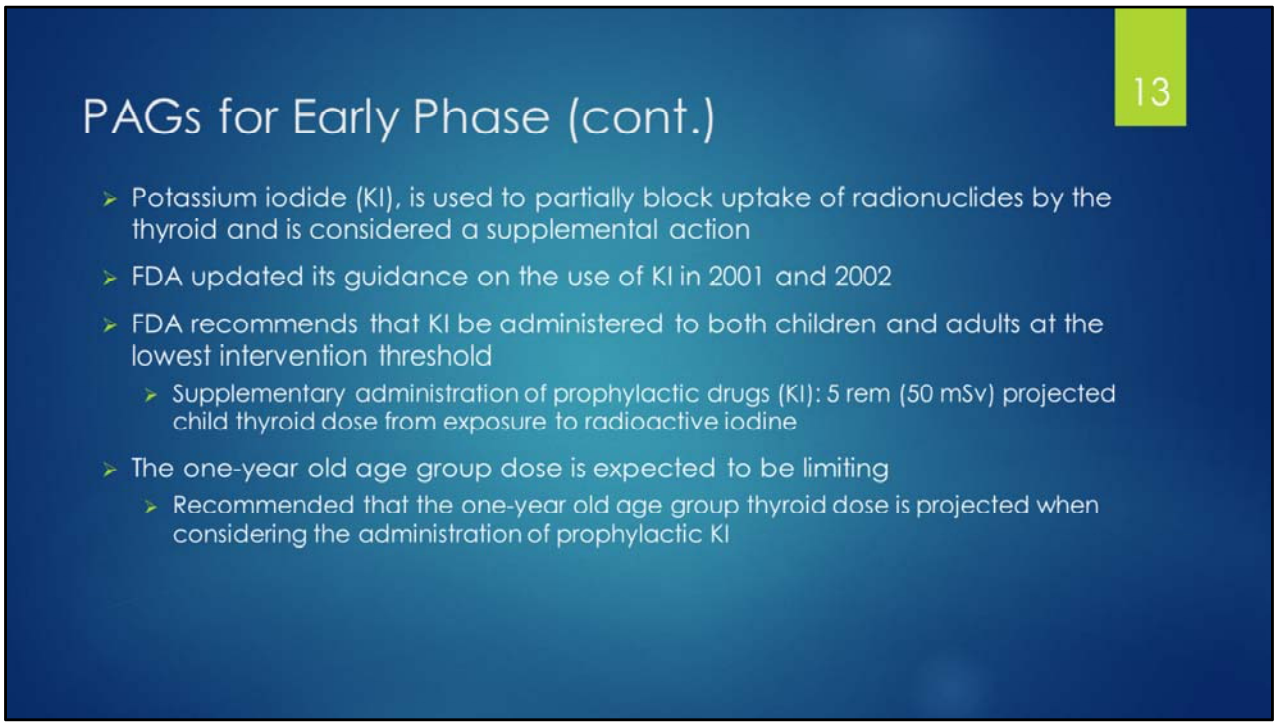
We had a final PAG Manual, except for the drinking water PAG, in December 2016. Fortunately, the water PAG was finalized soon after, and we were able to issue a complete final PAG Manual this last January.

The drinking water PAG is a non-regulatory guidance to protect the public in the event of a radiological incident that affects drinking water supplies. I'll go into that more in a moment.



In the early phase, sheltering-in-place and evacuation are the principal protective actions. These actions are meant to avoid inhalation of gases or particulates in an atmospheric plume and to minimize external radiation exposures. KI, also called "stable iodine," may be administered as a supplementary protective action if iodine is released. Some protective actions may begin prior to the release of radioactive material when there is advance notice. Decision examples:

- 1-5 rem (10-50 mSv) projected over four days. A decision to evacuate weighs anticipated dose against feasibility of evacuating within a determined time frame, along with the risks associated with the evacuation itself. There are several planning considerations included in the PAG Manual about whether to advise evacuation, or shelter in place.
- If iodine is released, KI should be considered as a supplementary protective action if the projected child thyroid dose exceeds 5 rem (50 mSV) –lower than the 1992 guidance. *HERE is where many are concerned about difference from old PAGs. No thyroid-based evacuation, but lower KI PAG only for communities that use it.*
- Emergency Worker: 5/10/25 rem (50/100/250 mSv) incurred over the response duration. The higher limits are based on task (e.g., protecting large populations or critical infrastructure or lifesaving).



Regarding sensitive subpopulations, after a release, child thyroid doses are roughly about twice as high as adult thyroid doses.

The former range recommended for thyroid dose-based evacuation (5 to 25 rem adult thyroid dose) is well covered by projections of whole body dose, with evacuation recommended at 1 to 5 rem (10 to 50 mSv) adult TED. This is in part because of the conservatism built into the PAG levels when they were set. It results in an appropriate level of dose avoidance for the whole community, including all age groups, for an emergency. Planners should add to their public messaging templates in advance some info to address concerns the public may have about how protective the PAG recommendations are for all members of an impacted community. This is another place where advice from the Advisory Team would be helpful.

Next we'll show the KI guidance from FDA.

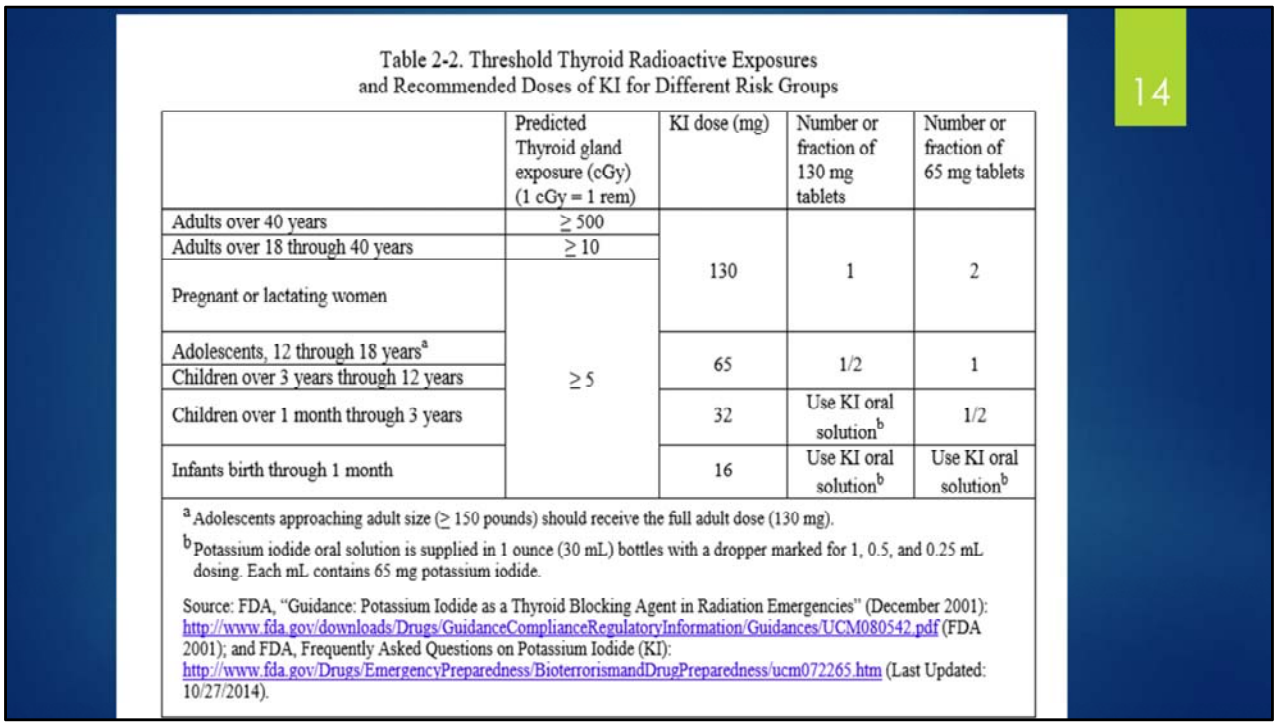


Table 2-2. Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups

	Predicted Thyroid gland exposure (cGy) (1 cGy = 1 rem)	KI dose (mg)	Number or fraction of 130 mg tablets	Number or fraction of 65 mg tablets
Adults over 40 years	≥ 500	130	1	2
Adults over 18 through 40 years	≥ 10			
Pregnant or lactating women	≥ 5			
Adolescents, 12 through 18 years[a]		65	1/2	1
Children over 3 years through 12 years				
Children over 1 month through 3 years		32	Use KI oral solution[b]	1/2
Infants birth through 1 month		16	Use KI oral solution[b]	Use KI oral solution[b]

[a] Adolescents approaching adult size (≥ 150 pounds) should receive the full adult dose (130 mg).

[b] Potassium iodide oral solution is supplied in 1 ounce (30 mL) bottles with a dropper marked for 1, 0.5, and 0.25 mL dosing. Each mL contains 65 mg potassium iodide.

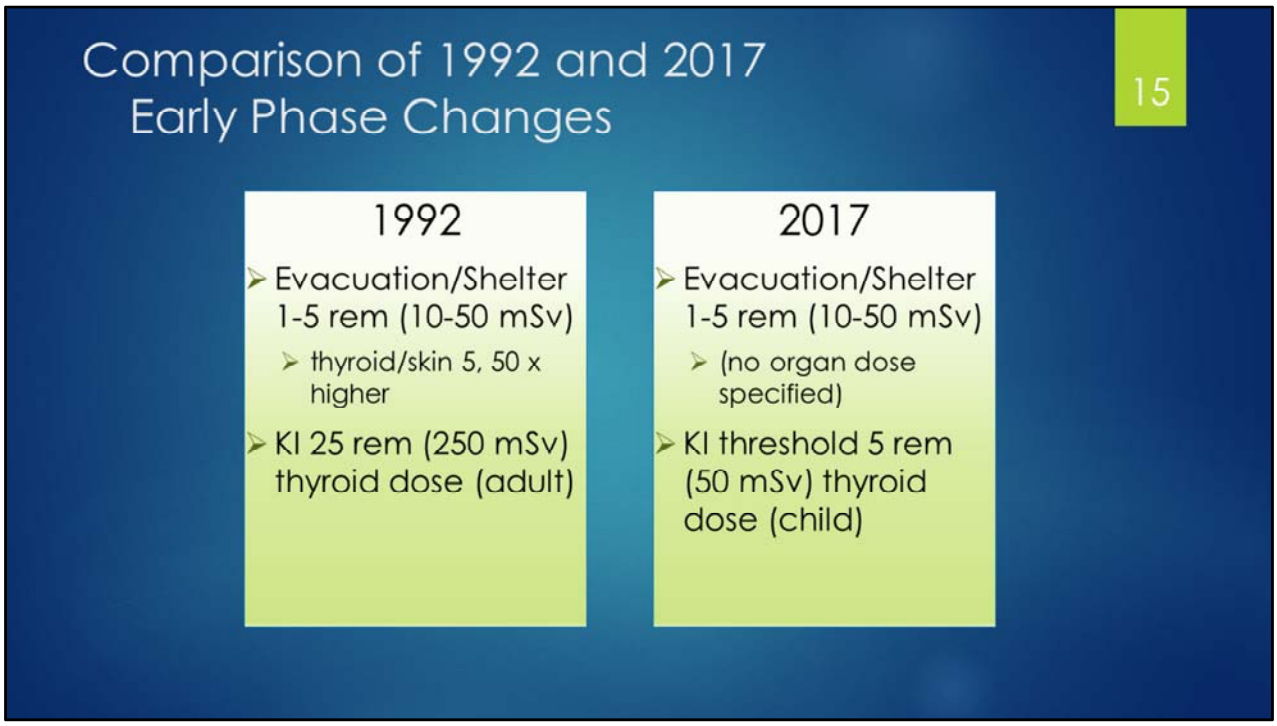
Source: FDA, "Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" (December 2001): http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080542.pdf (FDA 2001); and FDA, Frequently Asked Questions on Potassium Iodide (KI): http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm072265.htm (Last Updated: 10/27/2014).

14

FDA's guidance is medically correct for thresholds (PAGs) and dosages for each age group, but in their FAQs and in the PAG Manual, a simplified approach is allowed – where if your community uses KI, everyone can be advised to take KI if the child thyroid dose projection exceeds 5 rem CED. That is the lowest PAG here and conservatively covers everyone. Dosages, however, are still complicated.

Notes for readers, not speaker notes: Pregnant women should be given KI for their own protection and for that of the fetus, as iodine (whether stable or radioactive) readily crosses the placenta. However, because of the risk of blocking fetal thyroid function with excess KI, repeat dosing with KI of pregnant women should be avoided. Lactating females should be administered KI for their own protection, as for other young adults, and potentially to reduce the radioiodine content of the breast milk, but not as a means to deliver KI to infants, who should be administered KI directly.

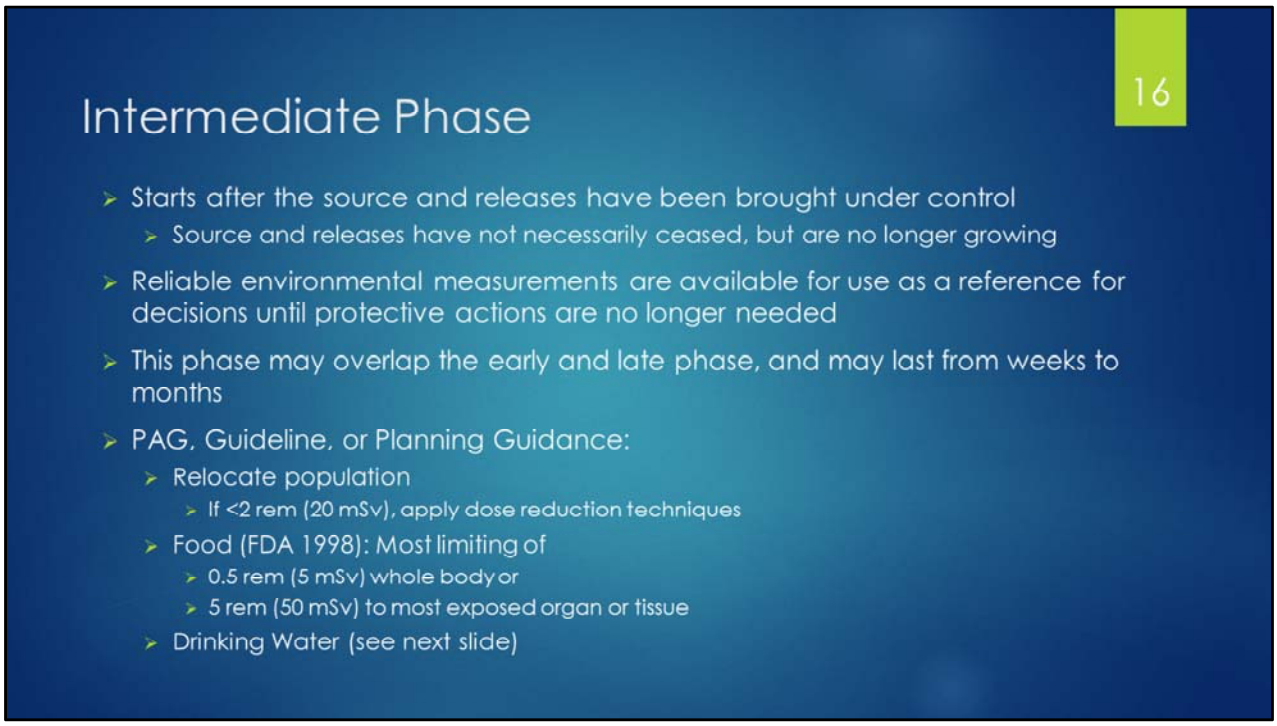
As for direct administration of KI, stable iodine as a component of breast milk may also pose a risk of hypothyroidism in nursing neonates. Therefore, repeat dosing with KI should be avoided in the lactating mother, except during continuing severe contamination. If repeat dosing of the mother is necessary, the nursing neonate should be monitored.



The following is a side-by-side comparison of the changes that were reflected in the 2013 Interim PAGs.

For the sheltering-in-place or evacuation of the public, the protective action guide range of 1-5 rem remained unchanged; however, in the 2013 PAG, there is no specific organ dose recommended.

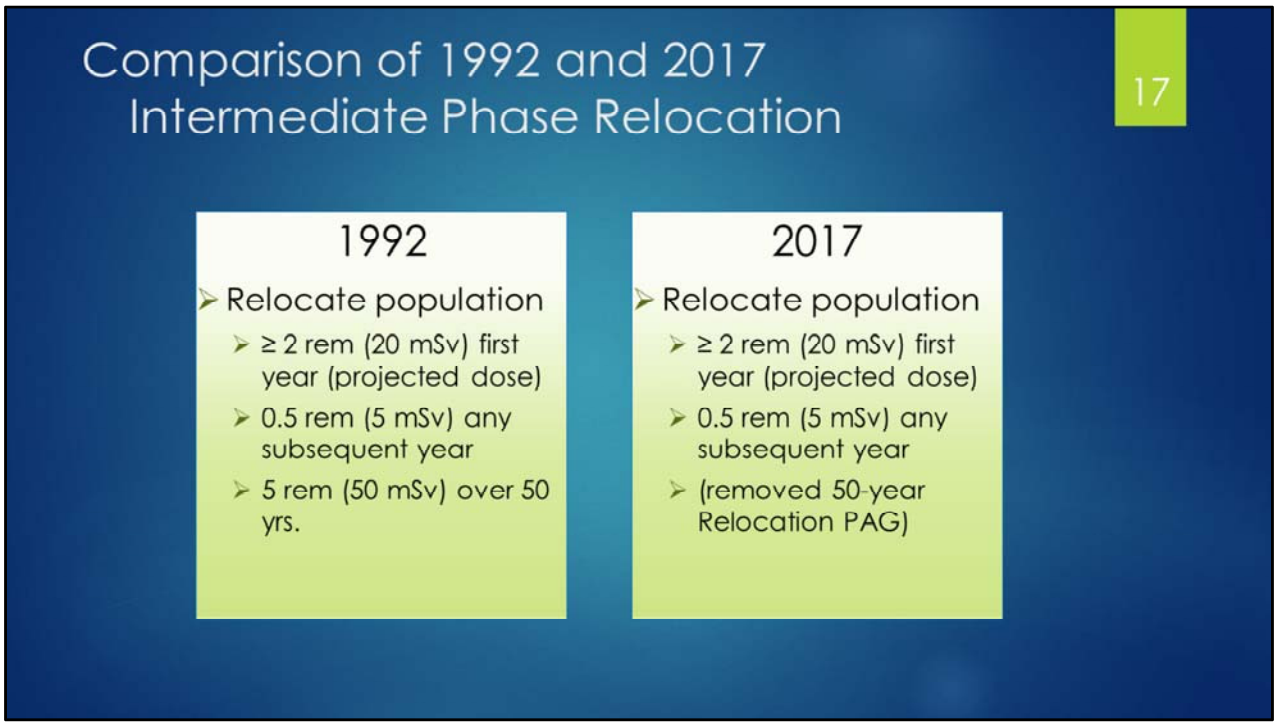
For communities that use it, (KI) should be considered as a supplementary protective action if projected child thyroid dose exceeds 5 mrem (50 millisieverts). This PAG is lower than the 1992 guidance. The lower dose, which the FDA adopted in 2001, is for protection of children based on early studies of Chernobyl exposure data.



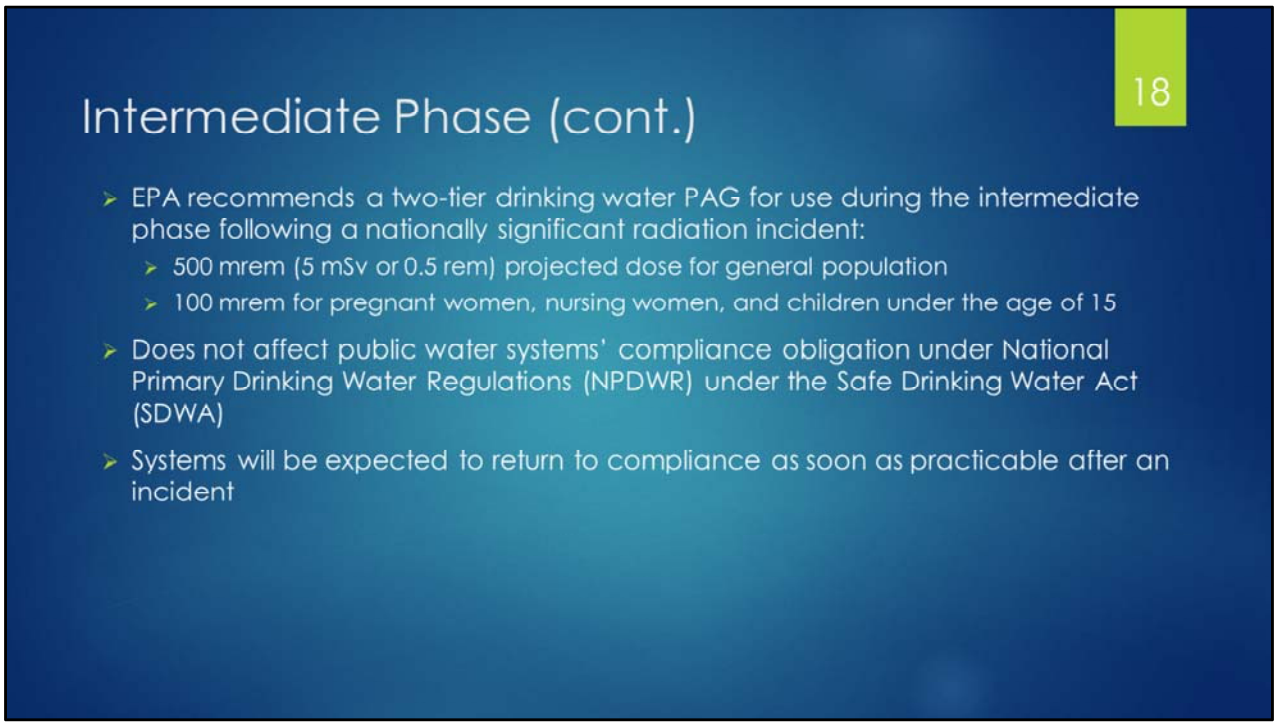
During the intermediate phase, relocation is the principal protective action against whole body external exposure from deposited radioactive material and internal exposure from inhalation of radioactive particulates. People may be relocated for weeks or months. During the intermediate phase, government officials may convene to discuss late phase cleanup and site restoration strategies. All actions taken during the early and intermediate phases should be considered with respect to the impact they may have on late phase remediation, such as avoiding the use of fixatives that could hinder surface decontamination at a later date

Decision examples:

- For relocation of the public, a 2 rem (20 mSv) PAG projected for the first year and 0.5 rem (5mSv) per any subsequent year projected dose are criteria for relocation. In this phase, with more federal support from FRMAC, scientists can run dose calculations with RESRAD-RDD or Turbo FRMAC; the user can choose sensitive age groups, or enter lower guidelines, if desired. Additionally, local decision makers can adapt the guidelines with incident specific considerations and implement variations as needed.



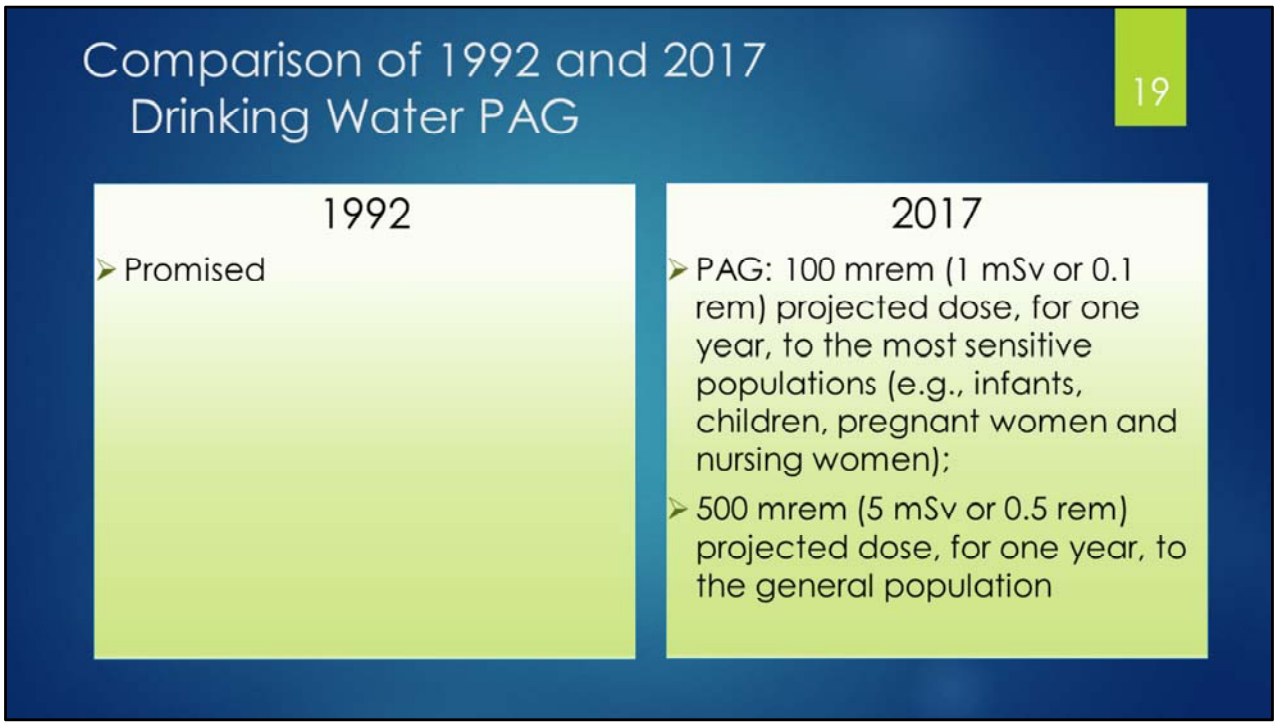
The following is a side-by-side comparison of the 1992 and 2013 intermediate phase changes between the 1992 and 2013 PAG manuals.
The Relocation of the Public PAG was adjusted to remove the 1992 provision about 5 rem over 50 years. The interagency PAGs Subcommittee found that there might be confusion between it and long-term cleanup goals… or that it might be misunderstood that relocation might have to last as long as 50 years!



For drinking water: EPA recommends a two-tier PAG: 500 mrem for the general population (anyone over age 15, excluding pregnant women and nursing women) and 100 mrem for pregnant women, nursing women and children.

Authorities have flexibility on how to apply the PAG. In some cases, they may find it prudent to use the PAG of 100 mrem as a target for the whole population, while in other circumstances, authorities may find that it makes sense to use both targets simultaneously. For example, emergency managers can use a two-tiered approach to focus on protecting the most sensitive population with limited alternate water resources. If bottled water must be rationed, for example, authorities may make the bottled water available to children, pregnant women and nursing women, and instruct the rest of the population to use a public drinking water supply that will not trigger the 500 mrem PAG.

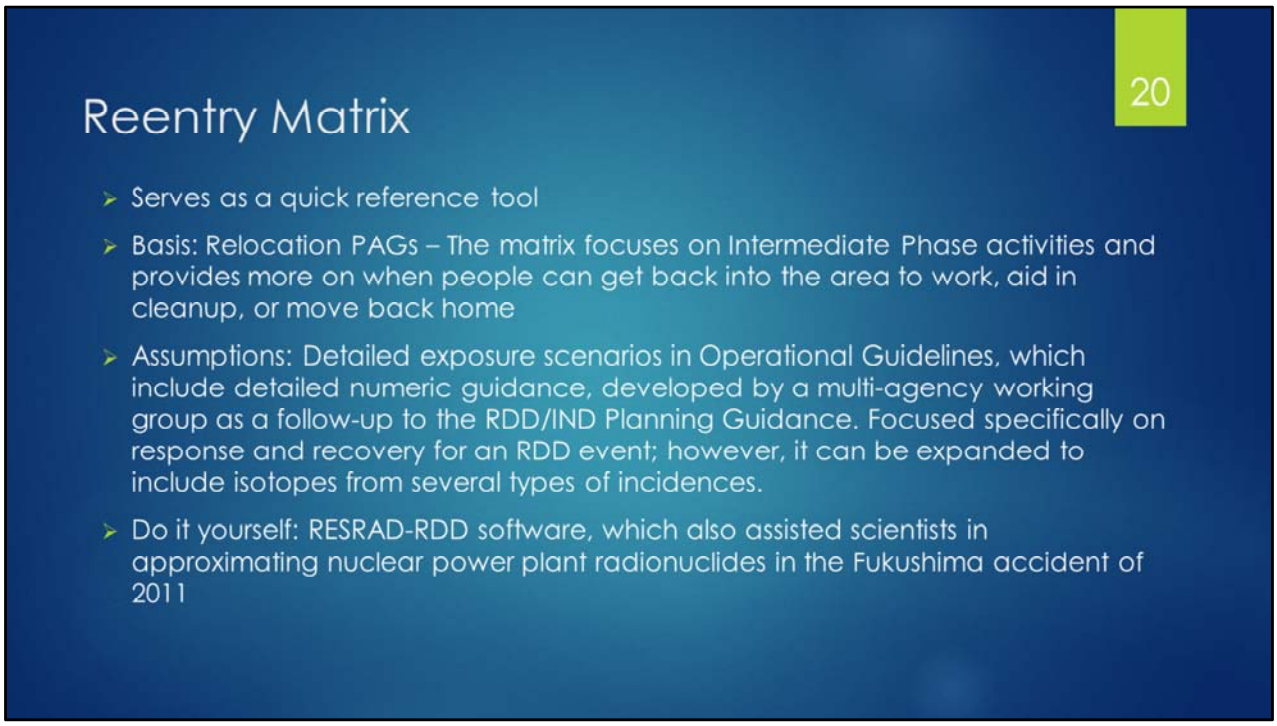
As stated above, the PAGs are intended as guidance only, and local authorities should take into account local circumstances (e.g., incident scope and community needs) when implementing any course of action to protect the public.



This is the first new PAG in many years, and we'll devote a separate series of webinars to talking about how you might implement this guidance in your plans.

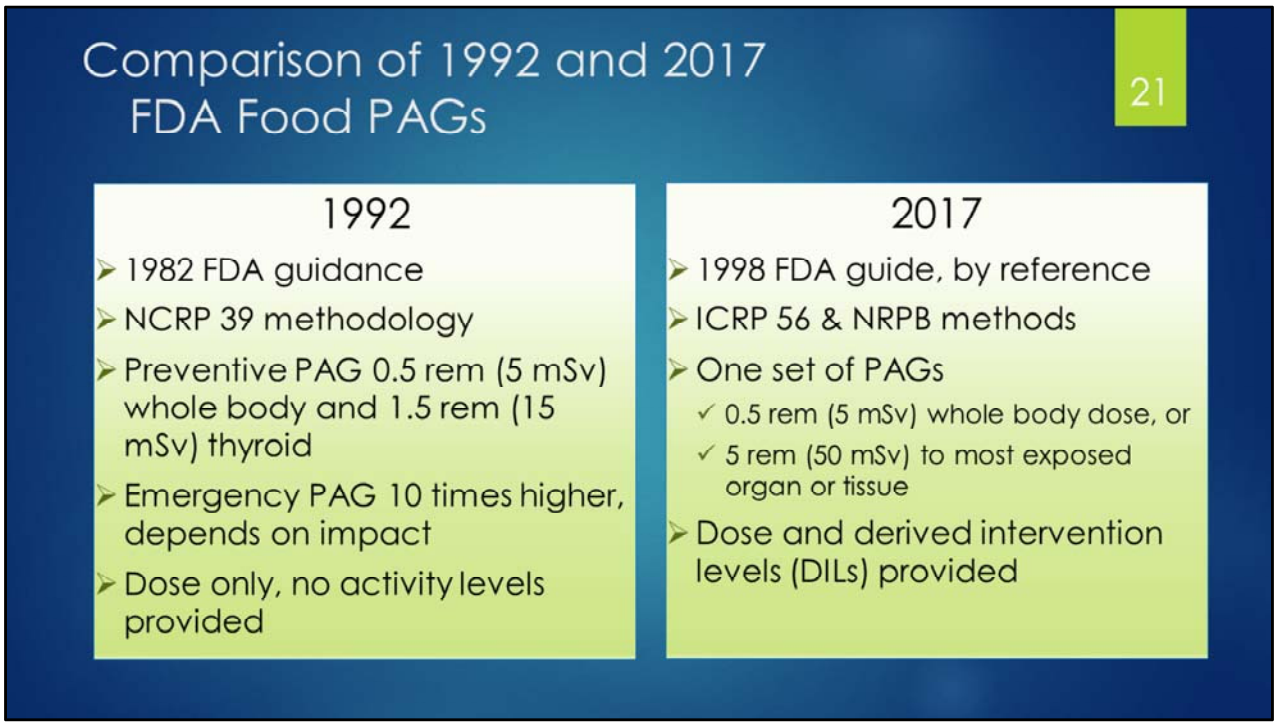
EPA got about 60,000 public comments on the proposal when it went out last year, and we made refinements to explain the approach, the water system options, and the derivation of the Derived Response Levels. FRMAC will acknowledge that it is complex to project doses to all the six age groups and use the most restrictive DRL.

The drinking water PAG will help federal, state, local and public water system officials make decisions about use of water during radiological emergencies. The drinking water PAG is for use only during an emergency; it does not substitute for compliance with EPA's National Primary Drinking Water Regulations (NPDWRs) for Radionuclides.



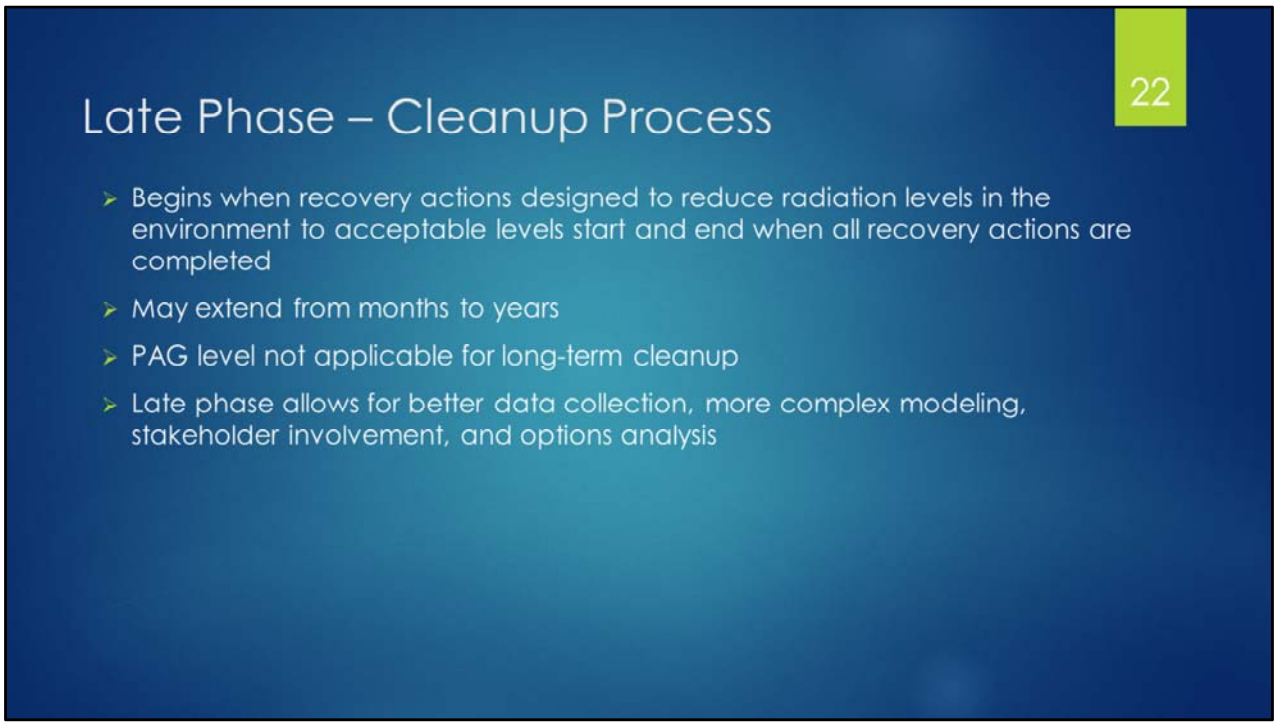
Another important highlight is the "Re-entry Matrix Following a Radiological Incident or Accident" found on pgs. 50 – 52. During the intermediate phase of a radiological emergency, individuals will need to enter the relocation area to collect their belongings, maintain or repair critical infrastructure, and to work on preliminary recovery activities. The Reentry Matrix provides a quick reference for public and worker dose guidelines and considerations for decontamination ongoing during this phase.

Operational guidelines include detailed numeric guidance, specifically discussions about applicable dose-based limits, timeframes and pathways of exposure related to reentry tasks. The term reentry is used for emergency workers and members of the public going into radiologically contaminated areas, temporarily, under controlled conditions. As part of the U.S. response to the Japanese Fukushima accident, scientists performed dose calculations to ensure that passengers and workers on train trips through contaminated areas do not exceed doses typically received from cosmic radiation during an international flight. DOE's Argonne National Laboratory scientists utilized the RESRAD-RDD tool and hand calculations to approximate doses from the NPP radionuclides.



(This is not really news, all orgs that use FDA PAGs had already implemented this update long ago, just here for completeness.)
NCRP = National Council on Radiation Protection
ICRP = International Commission on Radiological Protection
NRPB = National Radiological Protection Board (UK)

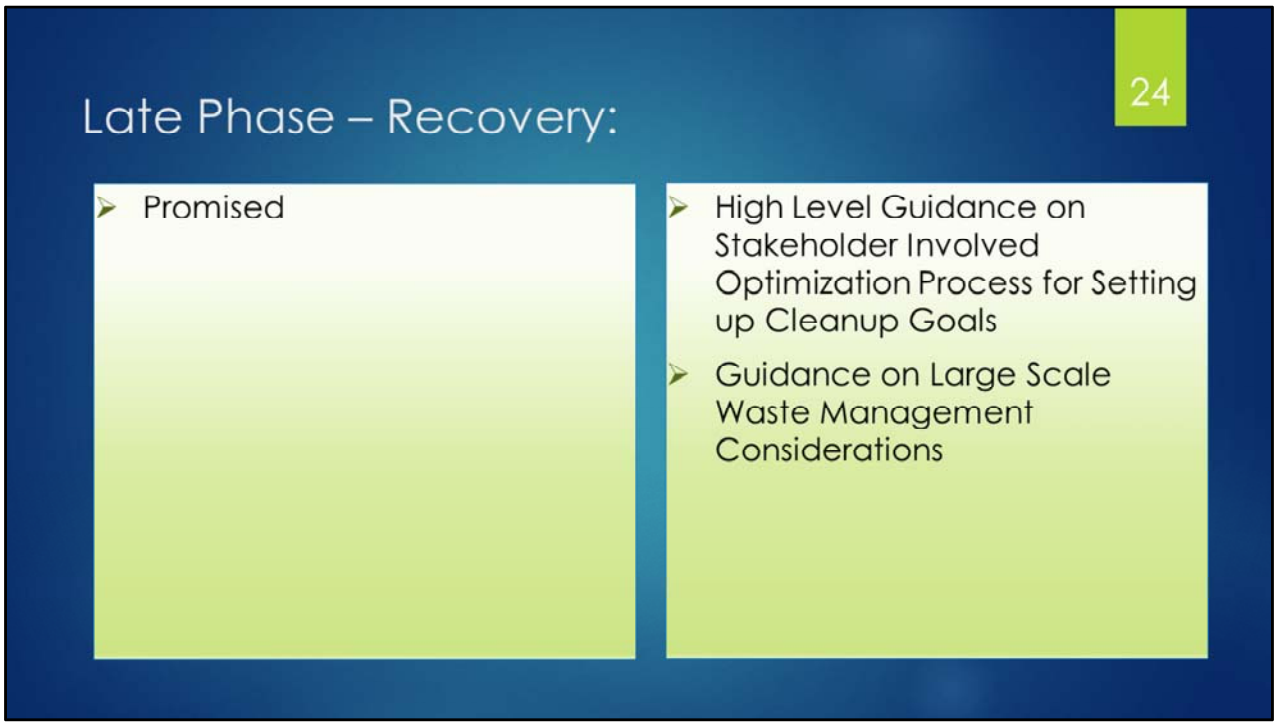
FDA provided Dose and Derived Intervention Levels (DILs), which is a concentration derived from the intervention level of dose at which introduction of protective measures should be considered. FDA always says that in a real event, incident-specific factors will be used to develop DILs appropriate for the situation. Note too that if FRMAC is generating Intervention Levels for any of the "non-FDA" radionuclides not explicitly address in FDA's 1998 guidance, then FDA's guidance is to use ICRP 60 to assess these radionuclides.



In the early phase decisions on an emergency will be made directly by elected public officials or their designees, with limited stakeholder involvement due to the immediate response needed in such a short timeframe.

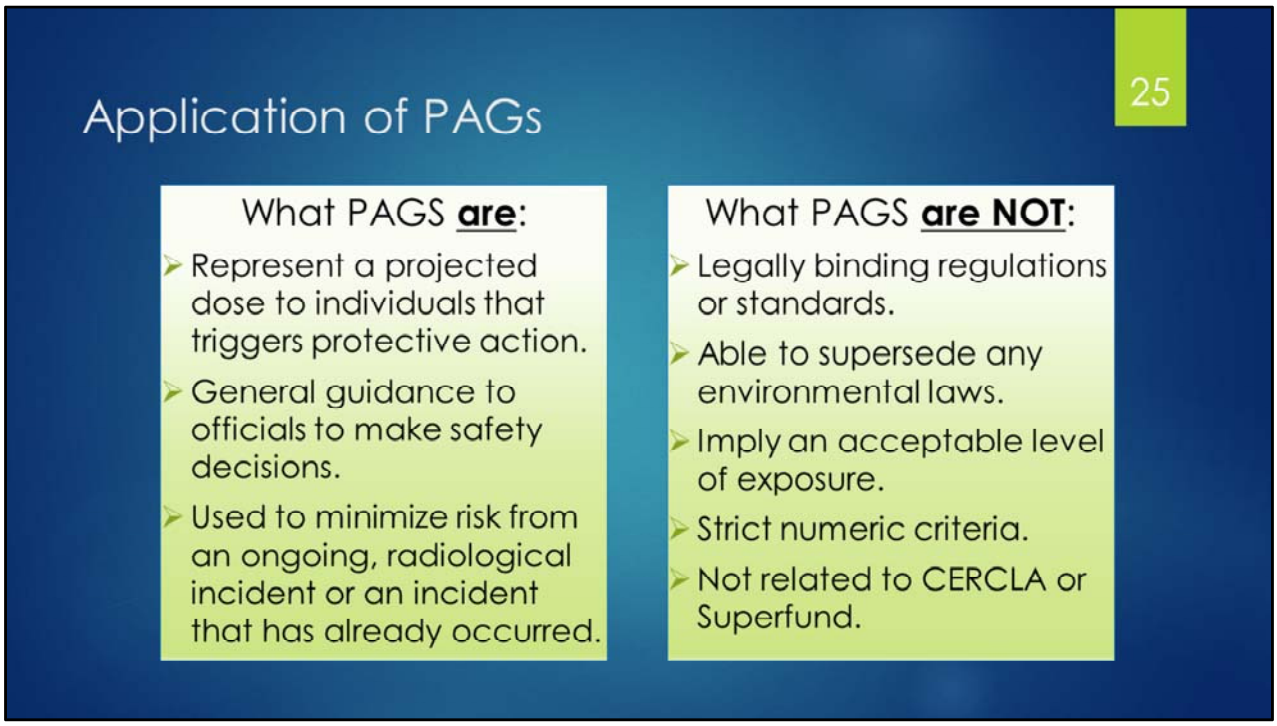
The late phase allows for additional time and an increased understanding of the situation, which presents opportunities to involve key stakeholders in providing sound, cost-effective cleanup recommendations that will protect human health and the environment.

Stakeholder involvement groups presents opportunities to involve members of the community in providing sound, cost-effective waste staging and disposal recommendations that will protect human health and the environment.
The new waste management discussion includes some possible solutions to a situation involving more radioactive waste than all of our US repositories could handle. It was co-authored by experts from DoD, DOE, EPA and others who would have a role in supporting states dealing with such an incident.



An example provided in the PAG manual includes a processes adapted closely from the "Planning Guidance for Protection and Recovery Following Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents" from the Department of Homeland Security; which describes a hypothetical organization to integrate federal cleanup support activities with state and local governments and the public.

Empaneling groups early on to represent stakeholders and interested community members will allow discussions to begin on setting goals, understanding risks and mitigative actions, and to set priorities. The guidance discusses setting up a Technical Working Group to provide support to a Stakeholder Working Group who will inform late phase priorities. By incorporating this guidance from DHS 2008, the final PAG Manual is superseding that DHS guidance.



Focus on avoided dose: Radiation emergency experts have protocols to make estimates of a projected public dose downwind for the first hours or days, and that is compared to PAGs.

The forward looking projection sometimes is hard to not compare to regulatory 'safe' levels – they are apples and oranges. The goal of using PAGs is to avoid the projected dose, by taking an action to take the source or the person away.

It is important to note that PAGs are not meant to be applied as strict numeric criteria, but rather as guidelines to be considered in the context of incident-specific factors.

- Not for radioactively contaminated sites
- Releases, incidents, or accidents
- Public protection is the focus
- Guidance, not regulatory
- Not related to CERCLA or Superfund
- Avoided dose ≠ safe limit to allow

Also note that several states have their own adaptations to PAGs

What's next is we will make these slides and speaker notes available to you all, and will work your questions into FAQs.

Go check out the new FAQs we've posted on the link here, and feel free to type your comments or questions into the Chat box. If you're going to speak up on the phone bridge, just make sure your computer speakers are muted so we don't get any echo!

We plan to host another series of webinars to discuss the drinking water PAG in more detail, soon.