SANDIA REPORT
SAND2014-1133
Unlimited Release
February 2014

Proposed Method to Calculate FRMAC Intervention Levels for the Assessment of Radiologically Contaminated Food and Comparison of the Proposed Method to the U.S. FDA's Method to Calculate Derived Intervention Levels

Terry Kraus, Sandia National Laboratories
Brian Hunt, Sandia National Laboratories

Prepared by
Sandia National Laboratories
Albuquerque, New Mexico 87185 and Livermore, California 94550

Sandia National Laboratories is a multi-program laboratory managed and operated by Sandia Corporation, a wholly owned subsidiary of Lockheed Martin Corporation, for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

Issued by Sandia National Laboratories, operated for the United States Department of Energy by Sandia Corporation.

Available to DOE and DOE contractors from
U.S. Department of Energy
Office of Scientific and Technical Information
P.O. Box 62
Oak Ridge, TN 37831

Telephone: (865) 576-8401
Facsimile: (865) 576-5728
E-Mail: reports@adonis.osti.gov
Online ordering: http://www.osti.gov/bridge

Available to the public from
U.S. Department of Commerce
National Technical Information Service
5285 Port Royal Rd.
Springfield, VA 22161

Telephone: (800) 553-6847
Facsimile: (703) 605-6900
E-Mail: orders@ntis.fedworld.gov
Online order: http://www.ntis.gov/help/ordermethods.asp?loc=7-4-0#online

SAND2014-1133
Unlimited Release
February 2014

Proposed Method to Calculate FRMAC Intervention Levels for the Assessment of Radiologically Contaminated Food and Comparison of the Proposed Method to the U.S. FDA's Method to Calculate Derived Intervention Levels

Terry Kraus and Brian Hunt
Nuclear Incident Response Program
Sandia National Laboratories
P.O. Box 5800
Albuquerque, New Mexico 87185-MS0791

Abstract

This report reviews the method recommended by the U.S. Food and Drug Administration for calculating Derived Intervention Levels (DILs) and identifies potential improvements to the DIL calculation method to support more accurate ingestion pathway analyses and protective action decisions. Further, this report proposes an alternate method for use by the Federal Emergency Radiological Assessment Center (FRMAC) to calculate FRMAC Intervention Levels (FILs). The default approach of the FRMAC during an emergency response is to use the FDA recommended methods. However, FRMAC recommends implementing the FIL method because we believe it to be more technically accurate. FRMAC will only implement the FIL method when approved by the FDA representative on the Federal Advisory Team for Environment, Food, and Health.

ACKNOWLEDGMENTS

The authors would like to acknowledge the contributions of Brenda Pobanz and Kristen Yu of NARAC at Lawrence Livermore National Laboratory in the development of the data products in this report.

CONTENTS

FIGURES

TABLES

1. INTRODUCTION

This document contains a review of the method recommended by the U.S. Food and Drug Administration (FDA), *Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies* (FDA 1998), to calculate the Derived Intervention Level (DIL) and identify potential improvements to the DIL calculation method to support more accurate ingestion pathway analyses and protective action decisions.

Further, this document proposes an alternate, Federal Emergency Radiological Assessment Center (FRMAC) Intervention Level (FIL), method to perform modified DIL-like calculations. The calculated DIL and FIL values are subsequently used to calculate the corresponding Ingestion Derived Response Levels (DRLs) using standard methods described in the FRMAC Assessment Manual (SNL 2012). For comparison purposes, the calculated DRLs are then plotted on data products using a hypothetical release at the Beaver Valley Nuclear Power Plant (BV NPP) and a radionuclide source term generated by NRC's RASCAL computer code.

The default approach of the FRMAC Assessment Division during an emergency response is to use the FDA-recommended methods to calculate DILs and DRLs. However, FRMAC recommends implementing the FIL method because we believe it to be more technically accurate. FRMAC will only implement the FIL method when approved by the FDA representative on the Federal Advisory Team for Environment, Food, and Health (Advisory Team).

Note: All DRLs presented in this document are calculated using the default Methods described in Volume 1 of the FRMAC Assessment Manual.

2. REVIEW OF FDA METHODOLOGY

Eq. 1 shows the method recommended by the FDA to calculate the DIL values, as presented in the FRMAC Assessment Manual (SNL 2012). In this paper the various inputs variables in Eq. 1 will be modified to show the effect on the DILs calculated using the FDA's recommended inputs compared to alternate input values.

$$DIL_{organ,age,i} = \frac{PAG_{organ}}{FDC_{age,i} * DFIR_{age} * EDI_{i} * IngDC_{organ,age,i}} \quad \text{(Eq. 1)}$$

$$\frac{\mu Ci}{kg_{wet}} = \frac{mrem}{unitless * \frac{kg_{wet}}{d} * d * \frac{mrem}{\mu Ci}}$$

where:

$DIL_{organ,age,i}$ = Derived Intervention Level, the concentration of radionuclide *i* in food at which the ingestion dose to the most sensitive population (age group) and target organ has the potential to equal the applicable ingestion PAG, $\mu Ci/kg_{wet}$;

PAG_{organ} = Protective Action Guide, as specified by the FDA or other Decision Makers, for the target organ, mrem;

$FDC_{age,i}$ = Fraction of Diet Contaminated, unitless;

$DFIR_{age}$ = Daily Food Intake Rate, the daily intake rate (as prepared for consumption, i.e. wet mass) for a specific age group, kg_{wet}/d;

EDI_i = Effective Days of Intake, the number of days required for the radionuclide to decay to <1% of its initial activity (maximum of 365), d; and

$$EDI_i = \frac{-\ln(0.01)}{\lambda_i} \quad \text{where } \lambda_i = \frac{\ln 2}{t_{1/2_i}}$$

NOTE: If the radionuclide half-life is greater than 54 days, the EDI_i = 365 days.

3.0 MODIFYING FDA'S DERIVED INTERVENTION LEVEL METHOD INPUTS AND ASSUMPTIONS:

This section identifies the assumptions made in the FDA DIL method that FRMAC believes can be modified to improve the accuracy of ingestion pathway analysis.

3.1 Modifying the Ingestion Dose Coefficients

The FDA 1998 guidance was developed before the ICRP 60+ dosimetry model was finalized and implemented. FDA's 1998 guidance uses ingestion dose coefficients (IngDCs) taken from ICRP 56 (ICRP 1989) and NRPB Publication GS7 (NRPB 1987) which have been superseded by updated IngDCs. This section demonstrates the impacts of modifying IngDC input variable on the calculated FIL and the corresponding Ingestion DRL. The red-highlighted IngDC variable in Eq. 2 indicates the input variable that is modified in the section.

$$FIL_{organ,age,i} = \frac{PAG_{organ}}{FDC_{age,i} * DFIR_{age} * EDI_{i} * IngDC_{organ,age,i}} \quad \text{(Eq. 2)}$$

Table 1 compares the ingestion DCs used in FDA's 1998 guidance to those of the ICRP 60+ series. This reveals that there are significant differences in IngDCs for certain radionuclides.

Table 1: Comparison of ingestion dose coefficients used in FDA 's guidance and those in ICRP 60+ (Kraus 2013a)

Radio-nuclide	Target Organ	Reference	Ingestion Dose Coefficient by Age Group (mSv/Bq)					
			3 month	1 yr	5 yr	10 yr	15 yr	Adult
Sr-89	LLI	FDA 1998 Table E-4	2.80E-05	1.40E-04	7.10E-05	4.80E-05	2.30E-05	2.10E-05
		ICRP 60+	1.53E-04	1.43E-04	7.21E-05	4.19E-05	2.31E-05	2.22E-05
Sr-89	Effective	FDA 1998 Table E-4	3.00E-05	1.50E-05	7.70E-06	5.20E-06	3.50E-06	2.20E-06
		ICRP 60+	3.59E-05	1.78E-05	8.88E-06	5.84E-06	3.97E-06	2.57E-06
I-131	Thyroid	FDA 1998 Table D-1	3.70E-03	3.60E-03	2.10E-03	1.10E-03	6.90E-04	4.40E-04
		ICRP 60+	3.66E-03	3.56E-03	2.06E-03	1.04E-03	6.81E-04	4.32E-04
I-131	Effective	FDA 1998 Table D-1	1.10E-04	1.10E-04	6.30E-05	3.20E-05	2.10E-05	1.30E-05
		ICRP 60+	1.84E-04	1.79E-04	1.04E-04	5.24E-05	3.42E-05	2.18E-05
Cs-137	Effective	FDA 1998 Table D-1	2.00E-05	1.10E-05	9.00E-06	9.80E-06	1.40E-05	1.30E-05
		ICRP 60+	2.10E-05	1.24E-05	9.68E-06	1.01E-05	1.34E-05	1.36E-05
Pu-239	Bone Surface	FDA 1998 Table D-1	1.80E-01	1.80E-02	1.80E-02	1.70E-02	1.90E-02	1.80E-02
		ICRP 60+	7.45E-02	7.62E-03	7.06E-03	6.84E-03	7.25E-03	8.23E-03
Pu-239	Effective	FDA 1998 Table D-1	1.40E-02	1.40E-03	1.10E-03	1.00E-03	9.80E-04	9.70E-04
		ICRP 60+	4.19E-03	4.22E-04	3.33E-04	2.71E-04	2.46E-04	2.51E-04

Table 2 compares the FDA's recommended DILs to the DILs calculated using the ICRP 60+ IngDCs. The ratio values in Table 2 reveal that there are significant differences between the DILs calculated using the FDA's IngDCs and the ICRP 60+ IngDCs. It is interesting to note that the most sensitive organ changes from the Whole Body (WB) to the Lower Large Intestine (LLI) for Ce-144 contaminated food when the ICRP 60+ IngDCs are used.

Table 2: Comparison of FDA's recommended DILs to DIL's calculated using ICRP 60+ ingestion dose coefficients and FDA's methodology (Kraus 2013b)

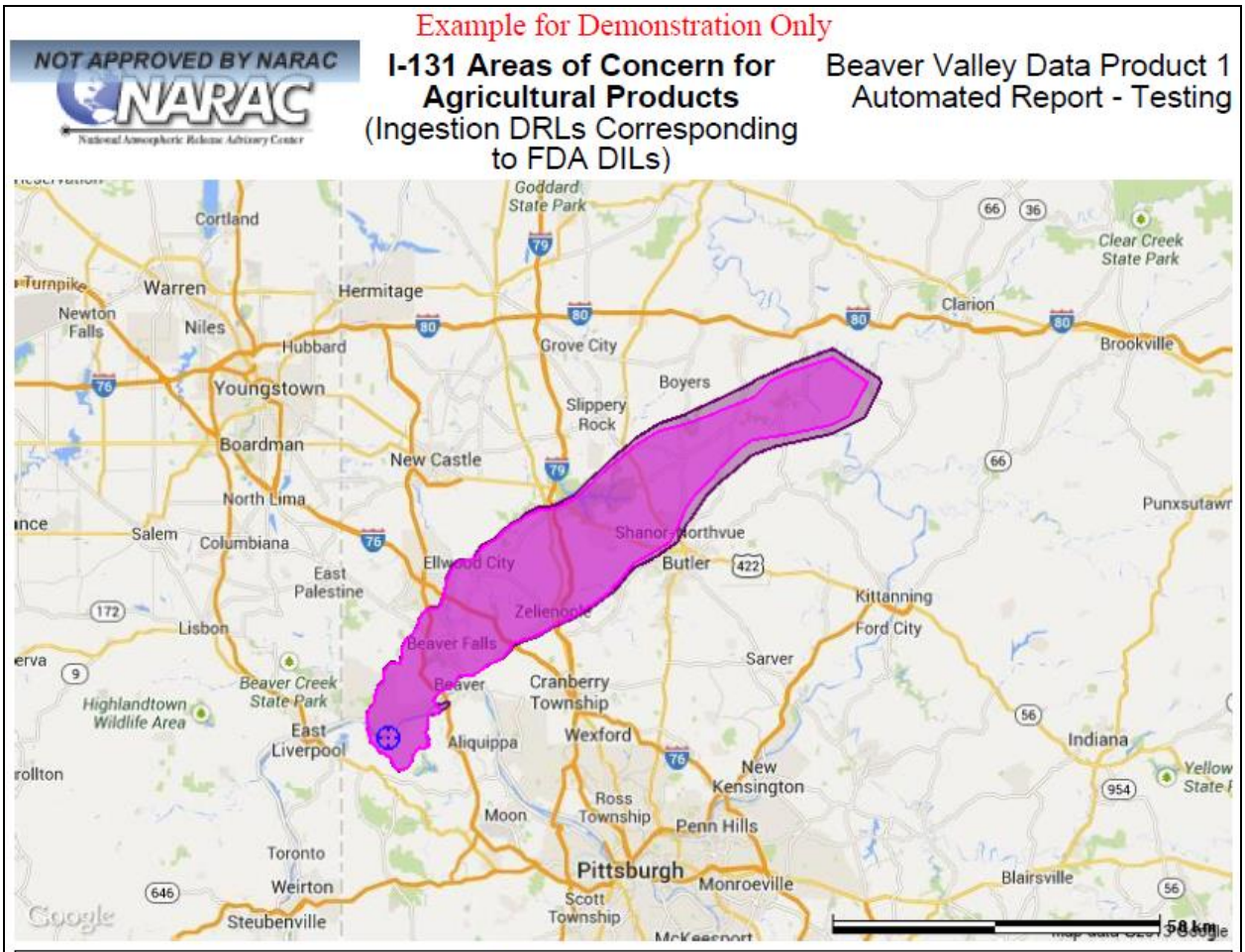
Radio-nuclide	FDA Recommendations and Dosimetry Model			ICRP 60 Dosimetry Model using FDA Methodology			Ratio of FDA to ICRP 60+ DIL
	Age Group	Organ	DIL (µCi/kg)	Age Group	Organ	DIL (µCi/kg)	
Am-241	Infant (3 month)	BS	5.40E-05	Infant (3 month)	BS	1.31E-04	0.41
Ba-140	Infant (3 month)	WB	1.86E-01	Infant (3 month)	WB	1.47E-01	1.27
Ce-141	Infant (3 month)	LLI	1.95E-01	Infant (3 month)	LLI	1.88E-01	1.04
Ce-144	Infant (3 month)	WB	1.35E-02	Infant (3 month)	LLI	1.42E-02	0.95
Cm-242	Infant (3 month)	BS	5.13E-04	Infant (3 month)	BS	1.07E-03	0.48
Cm-244	Infant (3 month)	BS	5.40E-05	Infant (3 month)	BS	1.84E-04	0.29
Cs-134	Adult	WB	2.51E-02	Adult	WB	2.48E-02	1.01
Cs-137	Adult	WB	3.67E-02	Adult	WB	3.51E-02	1.05
I-129	Ten Years Old	Thyroid	1.51E-03	One Year Old	Thyroid	6.21E-04	2.43
I-131	One Year Old	Thyroid	4.59E-03	One Year Old	Thyroid	5.13E-03	0.89
I-133	One Year Old	Thyroid	1.89E-01	One Year Old	Thyroid	1.96E-01	0.96
Nb-95	Infant (3 month)	WB	3.24E-01	Infant (3 month)	WB	3.70E-01	0.88
Np-237	Infant (3 month)	BS	1.08E-04	Infant (3 month)	BS	2.19E-04	0.49
Np-239	Infant (3 month)	LLI	7.57E-01	Infant (3 month)	LLI	2.58E+00	0.29
Pu-238	Infant (3 month)	BS	6.76E-05	Infant (3 month)	BS	1.59E-04	0.43
Pu-239	Infant (3 month)	BS	5.94E-05	Infant (3 month)	BS	1.45E-04	0.41
Pu-241	Infant (3 month)	BS	3.24E-03	Infant (3 month)	BS	9.08E-03	0.36
Ru-103	Infant (3 month)	WB	1.84E-01	Infant (3 month)	WB	2.13E-01	0.86
Ru-106	Infant (3 month)	WB	1.22E-02	Infant (3 month)	WB	1.29E-02	0.95
Sr-89	Infant (3 month)	WB	3.78E-02	Infant (3 month)	WB	3.28E-02	1.15
Sr-90	Fifteen Years Old	BS	4.32E-03	Fifteen Years Old	BS	2.85E-03	1.52
Te-132	Infant (3 month)	Thyroid	1.19E-01	Infant (3 month)	Thyroid	2.78E-01	0.43
Y-91	Infant (3 month)	LLI	3.24E-02	Infant (3 month)	LLI	3.12E-02	1.04
Zr-95	Infant (3 month)	WB	1.08E-01	Infant (3 month)	WB	1.26E-01	0.86
BS = Bone Surface, WB = Whole Body, LLI = Lower Large Intestine							

Table 3 summarizes the I-131 DIL and Milk Ingestion DRL calculated using the FDA's method, and the FIL and Ingestion DRL calculated using a modified method that uses ICRP 60+ IngDCs instead of the IngDCs used by the FDA. Although there are not significant differences in the values for I-131 calculated using the two different methods, Tables 1 and 2 reveal that, for some radionuclides, there are significant differences in ingestion DCs that FDA utilized compared to the ICRP 60+ Ingestion DC and these differences would lead to significantly different DILs/FILs and Ingestion DRLs for some radionuclides.

Table 3: I-131 FDA DIL and Milk Ingestion DRL Compared to I-131 FIL and Milk Ingestion DRL Calculated using FIL method with updated ingestion dose coefficients (Kraus 2013b)

Method	Modified Input for FIL Method	DIL (µCi/kg)	FIL (µCi/kg)	Ingestion DRL (µCi/m^2)	Ratio of DIL Ingestion DRL to FIL Ingestion DRL
FDA Method	NA	4.53E-03	NA	8.7E-03	0.99
Modified FIL method	IngDC	NA	4.58E-03	8.8E-03	

Figure 1 shows the projected area that may exceed the I-131 Ingestion DRLs (1-year old, thyroid) from a hypothetical release at the BV NPP using a RASCAL-generated source term. The contours are based on Ingestion DRLs calculated using the FDA's DIL method and the modified FIL method that uses ICRP60 dose coefficients. From Figure 1 it is evident that in this case, the changes in dose coefficients do not have a major impact on the projected areas that may exceed an Ingestion DRL.



Effects and Actions

	Description	Level (uCi/m2)	Extent	Area	Population
	Milk Ingestion DRL Using ICRP 60	>0.010	90.7km	1,043 km2	102,000
	FDA Milk Ingestion DRL	>0.009	92.4km	1,195 km2	107,000

Note: Areas and counts in the table are cumulative. Population Source = LandScan USA V1.0.

Figure 1: Comparison of I-131 Ingestion DRLs calculated using FDA's method and a modified FIL DRL method that uses ICRP60 ingestion dose coefficients.

3.2 Modifying the Modeling of Radioactive Decay

The FDA's 1998 guidance specifying how to calculate the Derived Intervention Level (DIL) does not accurately account for the radioactive decay that occurs over the consumption period. Although the DIL method does adjust the consumption period for short-lived radionuclides, it assumes no radioactive decay over the consumption period. Although, the FDA's method works reasonably well for long-lived radionuclides, this significantly overestimates the amount of radioactivity that is consumed over the consumption period when short-lived radionuclides are considered.

This section demonstrates the impacts of compensating for the radioactive decay that occurs over the consumption period on the calculated FIL and the corresponding Ingestion DRL. The red-highlighted Effective Days of Intake (EDI) variable in Eq. 3 indicates the input variable that is modified in the section.

$$FIL_{organ,age,i} = \frac{PAG_{organ}}{FDC_{age,i} * DFIR_{age} * EDI_i * IngDC_{organ,age,i}} \quad \text{(Eq. 3)}$$

Eq. 4 shows how the EDI term in Eq. 3 is modified to account radioactive decay that occurs over the consumption period.

$$FIL_{organ,age,i} = \frac{PAG_{organ}}{FDC_{age,i} * DFIR_{age} * \frac{1-e^{-\lambda_i t_c}}{\lambda_i} * IngDC_{organ,age,i}} \quad \text{(Eq. 4)}$$

where:

λ_i = Decay constant for radionuclide i, d^{-1};

t_c = Consumption Time, the length of the consumption period (default 365 days), d;

$\frac{1-e^{-\lambda_i t_c}}{\lambda_i}$ = Integrated decay over the length of consumption period, d and

Other variables are as previously defined.

Figure 2 compares the integrated dose from food contaminated at the FDA's DIL level by Cs-137, a long-lived radionuclide, as calculated using:

- the FDA's method (Equation 1) and
- a method that considers radioactive decay over the consumption period (Equation 4).

The FDA's method estimates the integrated ingestion does to the adult to be 5.0 mSv (500 mrem) Committed Effective Dose (CED) and this is in good agreement with the CDE of 4.9 mSv (490 mrem) that is estimated when radioactive decay over the consumption period is considered.

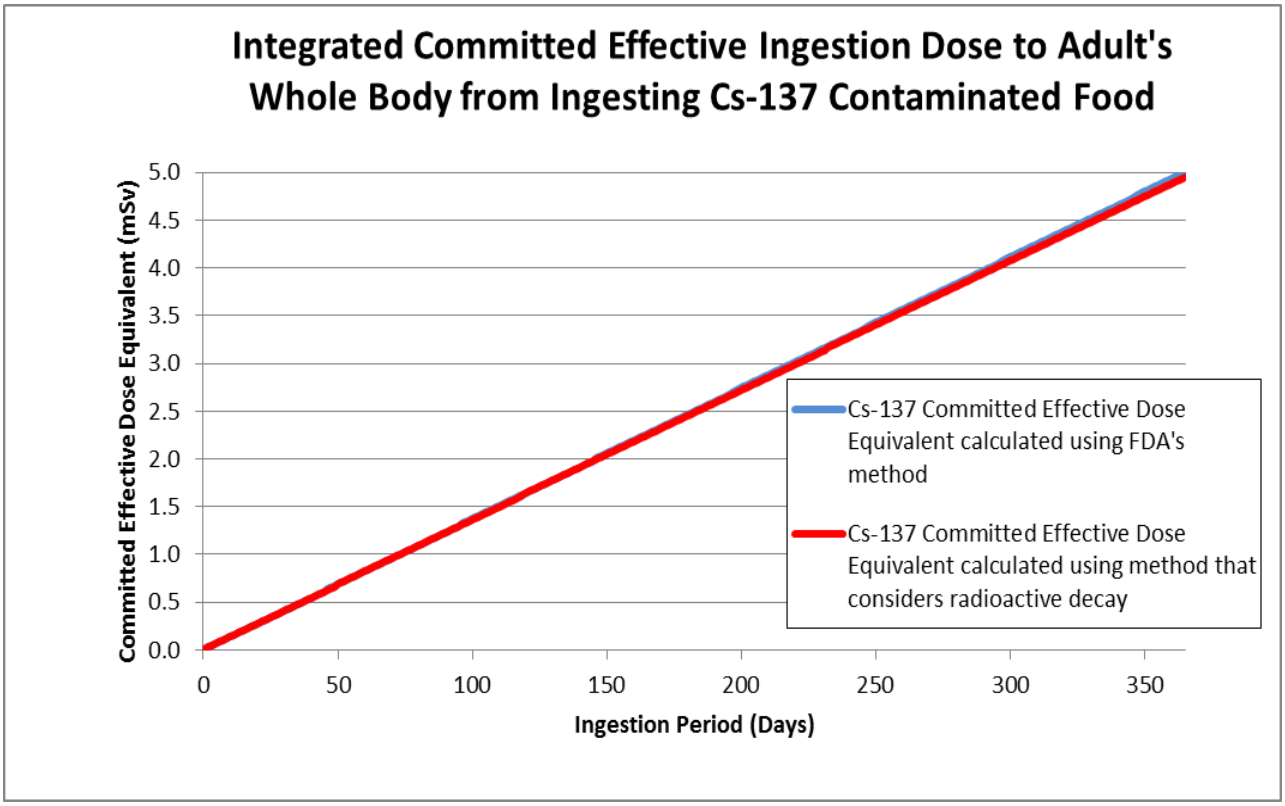


Figure 2: Integrated Ingestion Dose from Food Contaminated at the FDA's DIL for Cs-137 (Kraus 2013a)

Figure 3 compares the integrated dose from food contaminated at the FDA's DIL level for I-131, a short-lived radionuclide, as calculated using:

- the FDA's method (Equation 1) and
- a method that considers radioactive decay over the consumption period (Equation 4).

The FDA's method estimates the integrated ingestion dose to the 1-year old child's thyroid to be 51 mSv (5,100 mrem) Committed Dose Equivalent. The method that considers radioactive decay over the consumption period estimates the integrated ingestion dose to the thyroid to be 10 mSv (1,000 mrem) Committed Dose Equivalent. In this case the ingestion dose is over estimated by a factor of 5 when radioactive decay over the consumption period is not considered.

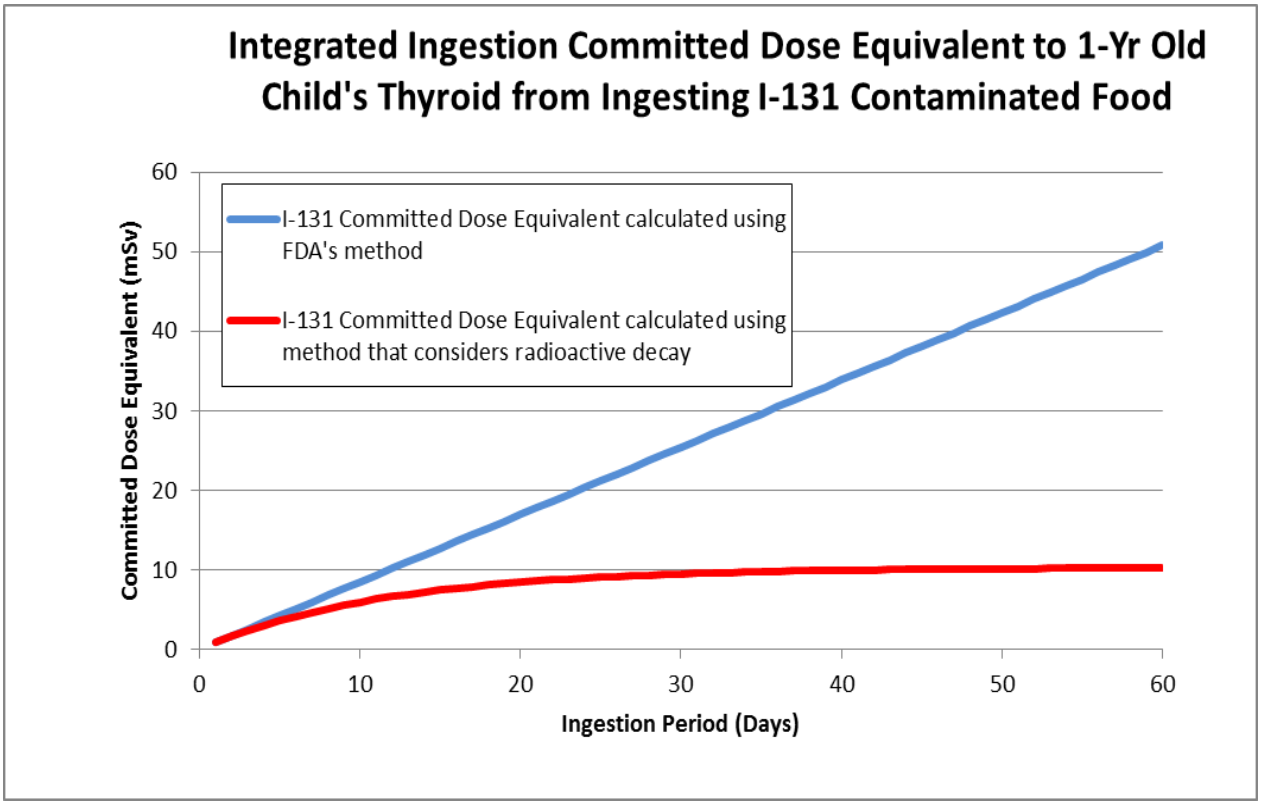


Figure 3: Integrated Ingestion Dose from Food Contaminated at the FDA's DIL for I-131 (Kraus 2013a)

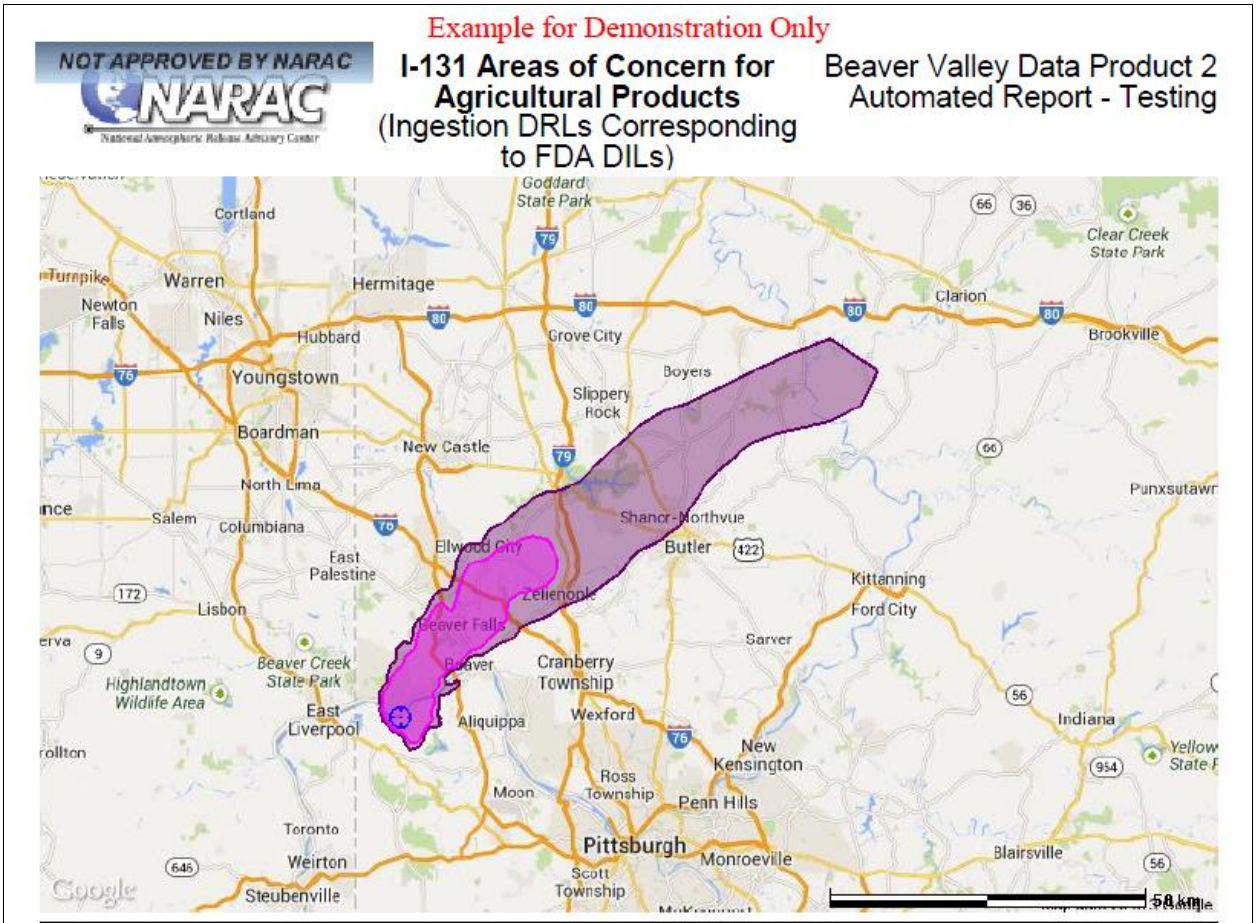
Figure 2 demonstrates that the FDA's methodology provides and accurate estimate of the ingestion dose when considering a radionuclide with a long half-life in comparison to the time period over with the contaminated food is consumed (consumption period). However, Figure 3 demonstrates that the FDA's methodology significantly overestimates the ingestion dose when considering a radionuclide with a short half-life in comparison to consumption period and the importance of accounting for radioactive decay that occurs over the consumption period when considering short-lived radionuclides such as I-131.

Table 4 summarizes the I-131 DIL and Milk Ingestion DRL calculated using the FDA's method, and the FIL and Ingestion DRL calculated using the modified method of Eq. 4 that compensates for the radioactive decay that occurs over the consumption period.

Table 4: I-131 FDA DIL and Milk Ingestion DRL compared to I-131 FIL and Milk Ingestion DRL Calculated using FIL Method that compensates for radioactive decay that occurs over the consumption period (Kraus 2013b)

Method	Modified Input for FIL Method	DIL (μCi/kg)	FIL (μCi/kg)	Ingestion DRL (μCi/m^2)	Ratio of DIL Ingestion DRL to FIL Ingestion DRL
FDA Method	NA	4.53E-03	NA	8.7E-03	0.19
Modified FIL method	Radioactive Decay Modeling	NA	2.34E-02	4.5E-02	

Figure 4 shows the projected area that may exceed the I-131 Ingestion DRLs (1-year old, thyroid) from a hypothetical release at the BV NPP using a RASCAL-generated source term. The contours are based on Ingestion DRLs calculated using the FDA's DIL method and the modified FIL method that compensates for radioactive decay over the consumption period. From Figure 4 it is evident that compensating for radioactive decay over the consumption period can have a large effect on the projected areas that may exceed an Ingestion DRL when short-lived radionuclides are considered.



Effects and Actions

	Description	Level (uCi/m2)	Extent	Area	Population
	Milk Ingestion DRL, corrected for radioactive decay	>0.05	36.0km	289 km2	52,600
	FDA Milk Ingestion DRL	>0.009	92.4km	1,195 km2	107,000

Note: Areas and counts in the table are cumulative. Population Source = LandScan USA V1.0.

Figure 4: Comparison of I-131 Ingestion DRLs calculated using FDA's method and a modified FIL DRL method that compensates for radioactive decay over the consumption period.

3.3 Modifying the Dietary Intake Rate Assumption

FDA's 1998 guidance assumes that 30% of the entire diet is contaminated food for all radionuclides except I-131, I-133, Te-132 and Np-239 for which it is assumed that 100% of the

3-month infant's and 1-yr old child's entire diet is contaminated. More accurate ingestion analyses could be made by considering the actual intake of the *category of food* that is contaminated. For example when assessing contaminated milk, it would be more accurate to assume that 100% of the 1-yr old child's *fresh cow's milk* or *total dairy intake* is contaminated milk instead of assuming that 100% of the 1-yr old child's *entire diet* is contaminated milk.

This section demonstrates the impacts of modifying the Daily Food Intake Rate (DFIR) input variable in Eq. 1. The red-highlighted variable in Eq. 5 indicates the input variables that are modified in the section.

NOTE: because this analysis considers I-131 and the 1-year old child, the FDA's assumed value for the FDC of 1 was used to calculate the modified FIL and the corresponding Ingestion DRL.

$$FIL_{organ,age,i} = \frac{PAG_{organ}}{FDC_{age,i} * DFIR_{age} * IngDC_{organ,age,i} * EDI_{i}} \quad \text{(Eq. 5)}$$

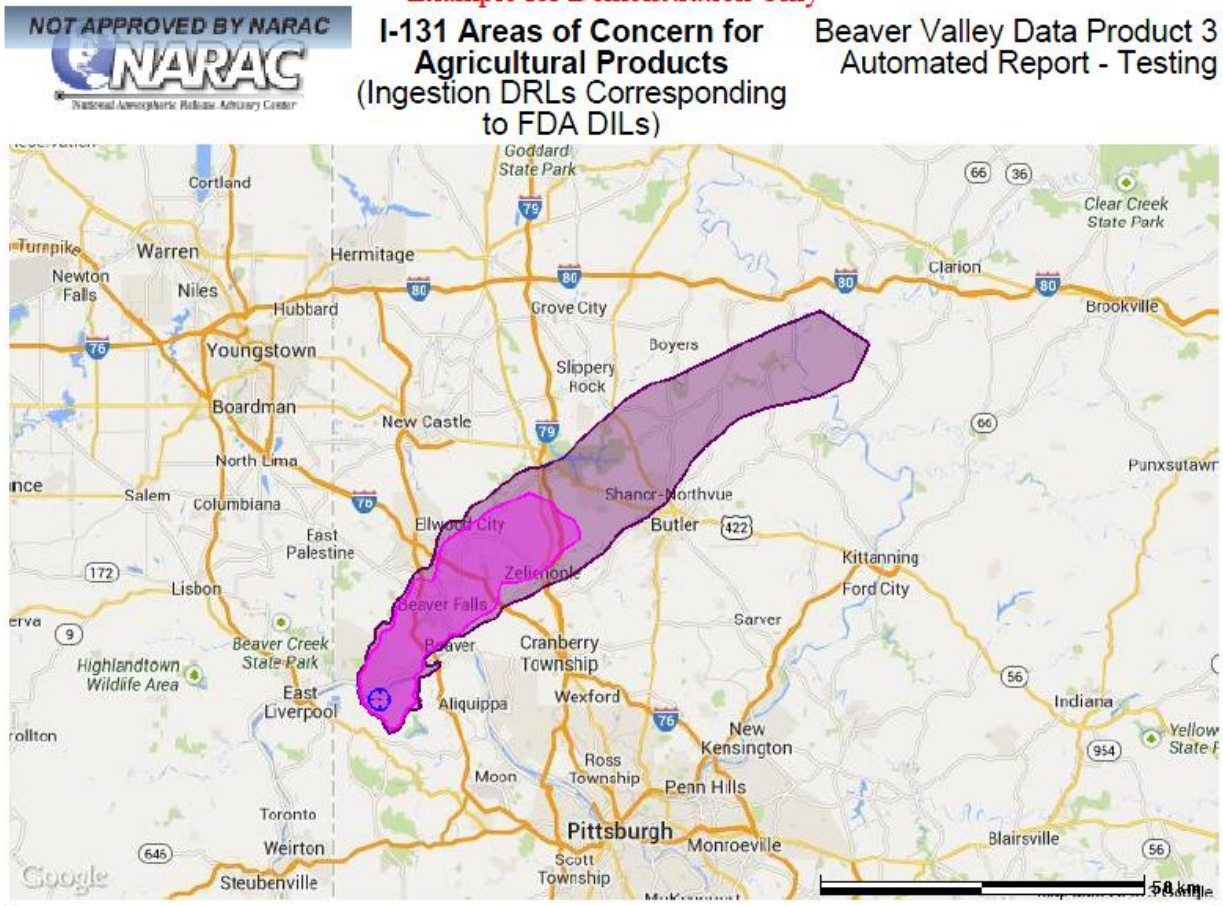
Table D-3 from FDA's 1998 guidance indicates that the 1-yr old child's total diet (all foods) daily intake rate is 1.38 kg/day. Tables D-2 and D-3 from FDA's 1998 guidance indicates that the 1-yr old child's total dairy daily intake rate is 0.49 kg/day. Table 4 summarizes the I-131 DIL and Milk Ingestion DRL calculated using the FDA's method, and the FIL and Ingestion DRL calculated using a modified method that assumes the amount of contaminated food that is consumed corresponds with the category of food that is contaminated.

Table 5 summarizes the I-131 DIL and Milk Ingestion DRL calculated using the FDA's method, and the FIL and Ingestion DRL calculated using a modified FIL method that uses food intake rate assumptions that correspond to the category of food that is contaminated. It is assumed that the child's *total dairy intake* (0.49 kg/d) is contaminated.

Table 5: I-131 FDA DIL and Milk Ingestion DRL compared to I-131 FIL and Milk Ingestion DRL calculated using the FIL Method that assumes that the amount of contaminated food that is consumed corresponds with the category of food that is contaminated (Kraus 2013b)

Method	Modified Input for FIL Method	DIL (µCi/kg)	FIL (µCi/kg)	Ingestion DRL (µCi/m^2)	Ratio of DIL Ingestion DRL to FIL Ingestion DRL
FDA Method	NA	4.53E-03	NA	8.7E-03	0.36
Modified FIL method	Intake Rate Assumption	NA	1.27E-02	2.4E-02	

Figure 5 shows the projected area that may exceed the I-131 Ingestion DRLs (1-year old, thyroid) from a hypothetical release at the BV NPP using a RASCAL-generated source term. The contours are based on Ingestion DRLs calculated using the FDA's DIL method and the modified FIL method that assumes that the amount of contaminated food that is consumed corresponds with the category of food (i.e., total dairy) that is contaminated. From Figure 5 it is evident that using more realistic assumptions of the amount of contaminated food that is consumed can have a large effect on the projected areas that may exceed an Ingestion DRL.



Effects and Actions

	Description	Level (uCi/m2)	Extent	Area	Population
	Milk Ingestion DRL, using total dairy intake rate	>0.02	40.3km	420 km2	65,900
	FDA Milk Ingestion DRL	>0.009	92.4km	1,195 km2	107,000

Note: Areas and counts in the table are cumulative. Population Source = LandScan USA V1.0.

Figure 5: Comparison of I-131 Ingestion DRLs calculated using FDA's method and a modified FIL DRL method that sets the amount of contaminated food that is consumed to be consistent with the category of food that is contaminated.

3.4 Modifying the Ingestion Dose Coefficients, Radioactive Decay Modeling and Dietary Intake Rates

This section demonstrates the impacts of using the complete FIL method (i.e., modified IngDC, compensation for radioactive decay over the consumption period and modified intake rate assumption) to calculate the DIL and the corresponding Ingestion DRL. The red-highlighted variables in Eq. 6 indicate the input variables that are modified in the section.

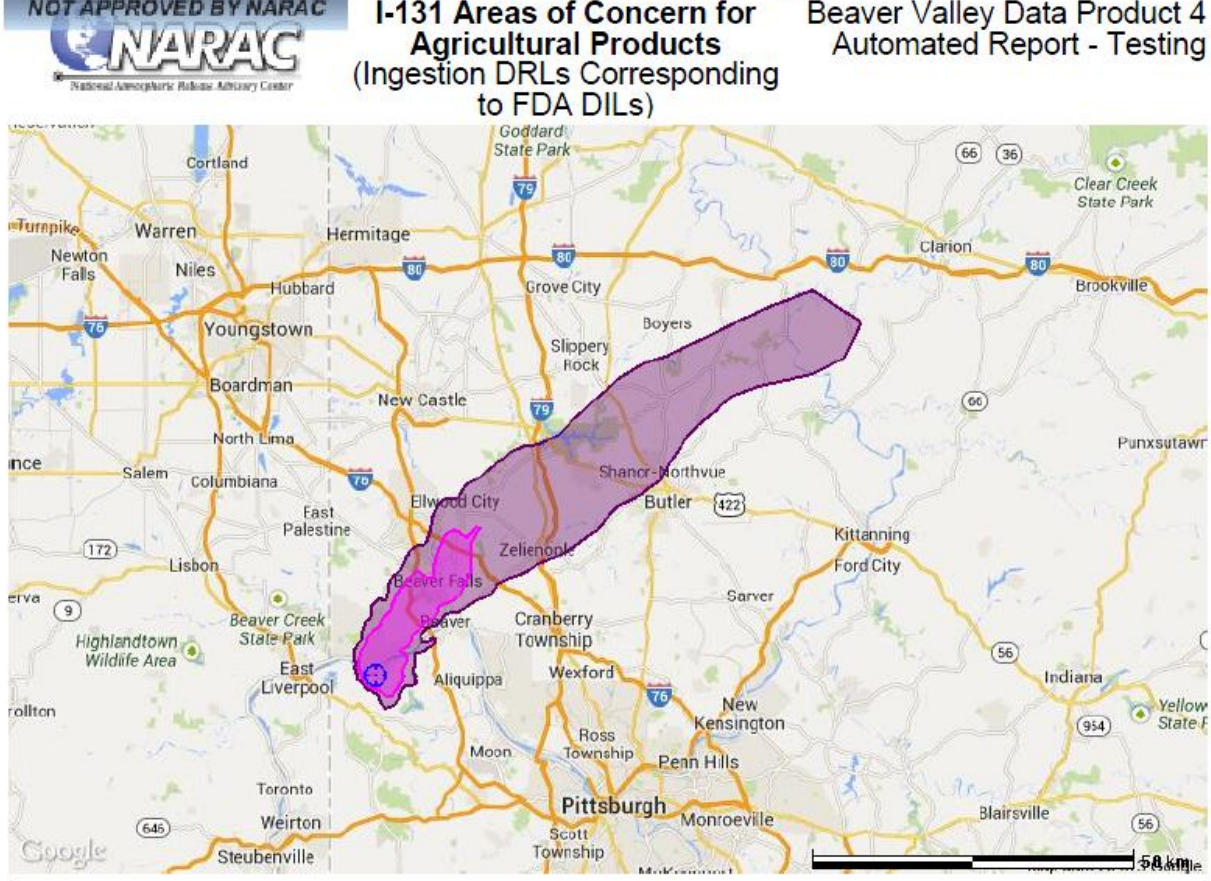
$$FIL_{organ,age,i} = \frac{PAG_{organ}}{FDC_{age,i} * DFIR_{age} * IngDC_{organ,age,i} * \frac{1-e^{-\lambda_i t_c}}{\lambda_i}} \quad \text{(Eq. 6)}$$

Table 6 summarizes the I-131 DIL and Milk Ingestion DRL calculated using the FDA's method, and the FIL and Ingestion DRL calculated using the complete FIL method that uses modified IngDCs, compensates for radioactive decay over the consumption period and modified food intake rate assumptions that correspond to the category of food that is contaminated.

Table 6: FDA DIL and Ingestion DRL Compared to FIL and Ingestion DRL Calculated using Complete FIL Method (Modified Ingestion Dose Coefficients, Radioactive Decay Compensation and Modified Food Intake Rate Assumption) (Kraus 2013b)

Method	Modified Input for FIL Method	DIL (µCi/kg)	FIL (µCi/kg)	Ingestion DRL (µCi/m^2)	Ratio of DIL Ingestion DRL to FIL Ingestion DRL
FDA Method	NA	4.53E-03	NA	8.7E-03	0.067
Modified FIL method	Complete FIL Method	NA	6.62E-02	1.3E-01	

Figure 6 shows the I-131 Ingestion DRLs for I-131 as calculated using the FDA's method and the complete FIL method. From Figure 6 it is evident that using updated IngDCs, compensating for radioactive decay over the consumption period and more realistic assumptions of the amount of contaminated food that is consumed can have a large effect on the projected areas that may exceed an Ingestion DRL.



Effects and Actions

	Description	Level (uCi/m2)	Extent	Area	Population
	Milk Ingestion DRL, complete FIL DRL method	>0.1	27.7km	164 km2	36,400
	FDA Milk Ingestion DRL	>0.009	92.4km	1,195 km2	107,000

Note: Areas and counts in the table are cumulative. Population Source = LandScan USA V1.0.

Figure 6: Comparison of I-131 Ingestion DRLs calculated using FDA's method and the complete FIL DRL method.

3.5 Modifying Derived Intervention Level Method to Include all Radionuclide Contaminants

The current DIL methods specified by FDA's guidance only considers the radiological impacts from one radionuclide. Some radiological release scenarios such as a NPP accident have the

potential to release multiple radionuclides that could contaminate food grown in the area impacted by the released plume. Failure to consider all radionuclide contaminants can significantly underestimate the dose from eating contaminated foods.

NRC's RASCAL computer code was used to generate a hypothetical source term from the BV NPP and this source term was used to perform an ingestion pathway assessment of food contaminated by this release scenario. The BV NPP release includes 69 parent radionuclides. The FIL and the corresponding FRMAC Ingestion DRL were calculated for each parent radionuclide using the complete FIL method described above and the standard FRMAC methods for calculating Ingestion DRLs (SNL 2012). Key inputs and assumptions for the FIL method include:

- use of ICRP 60+ IngDCs,
- compensation for radioactive decay, that occurs from harvest to until the food is ready for consumption (time to market), (1 day for fresh produce and 2 days for milk),
- compensation for radioactive decay that occurs over the consumption period (365 days),
- use of food intake rates that are specific to the age group and category of food that is contaminated, (1-year old child's total diary intake is 0.49 kg/d and adult's daily intake of exposed produce is 8.3E-3 kg/day), and
- assumption that all food of the category under consideration is contaminated.

Table 7 summarizes two detailed analyses of the dose impacts of the entire NPP release mixture:

- mature crop (exposed produce) comparing values for Cs-137 and
- milk comparing values I-131.

Table 7: Comparison of FDA DILs and Ingestion DRLs to Modified FRMAC FILs and Ingestion DRLs (Kraus 2013c)

Food Category	Exposed Produce			Milk
Marker Radionuclide	Cs-137			I-131
Age Group	Adult			1-Yr Old
Organ	Whole Body			Thyroid
Applicable FDA PAG (rem)	0.5			5
Consumption Period (days)	365	200	90	60
FDA Method Analyses				
DIL (µCi/kg)	3.70E-02	NA	NA	4.60E-03
DRL (µCi/m^2)	3.67E-01	NA	NA	8.80E-03
Calculated Dose [1] (rem)	19.8	NA	NA	5.1
FRMAC Intervention Level Method Analyses				
FIL (µCi/kg)	2.93E-02	3.42E-02	3.92E-02	6.51E-02
DRL (µCi/m^2)	2.93E-01	3.42E-01	3.92E-01	1.25E-01
Calculated Dose [2] (rem)	0.5	0.5	0.5	5

[1] FDA method. Food contaminated at FDA DIL for marker radionuclide with other released radionuclides from the NPP mixture scaled appropriately.

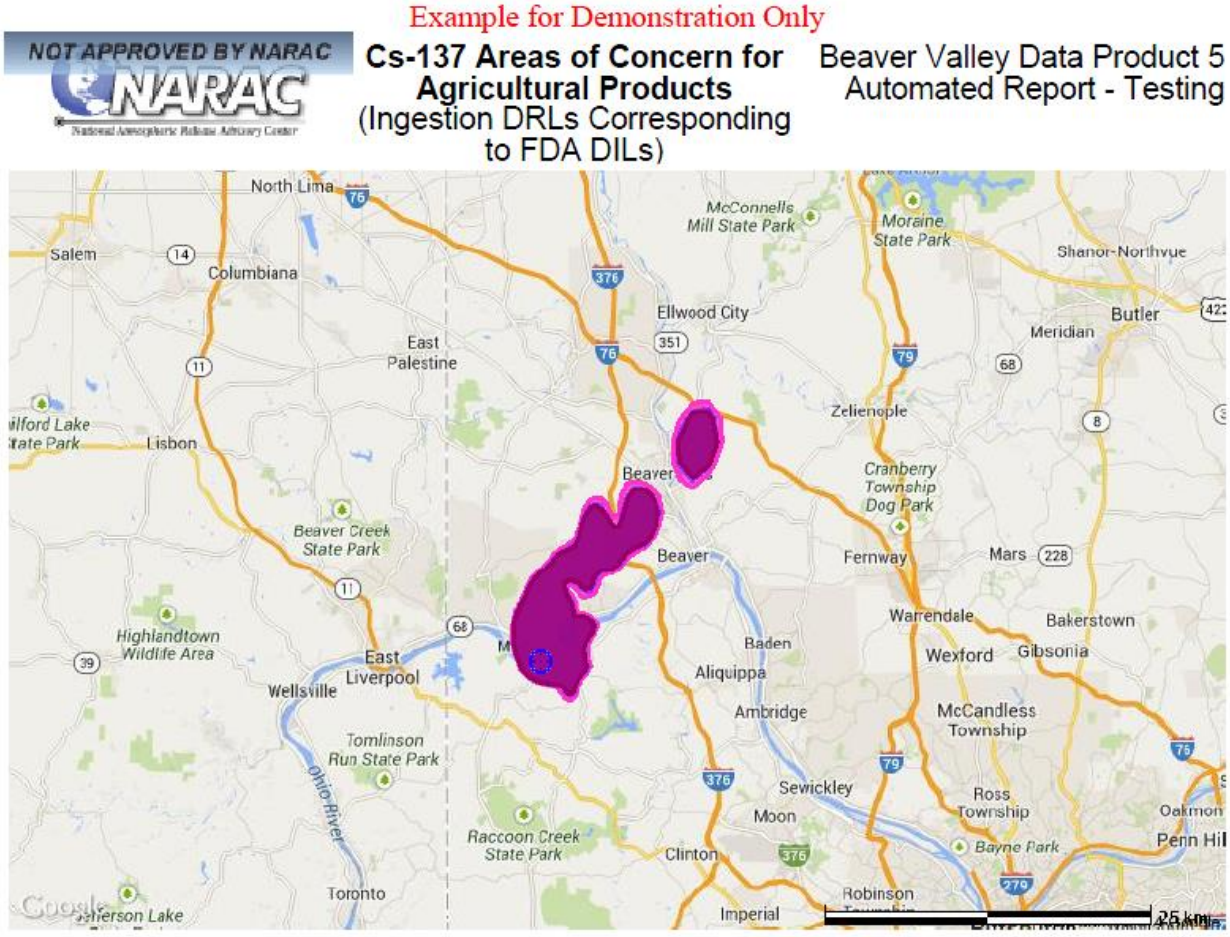
[2] Complete FIL method. Food contaminated at FIL for marker radionuclide with other released radionuclides from the NPP mixture scaled appropriately.

Figure 7 shows the areas that exceed the Mature Crop (exposed produce) DRL based on these calculations.

Figure 8 shows the areas that exceed the Milk Ingestion DRL based on these calculations.

Figure 7 shows three contours:

1. 0.39 µCi/m^2 Cs-137, Mature Crop Ingestion DRL calculated using the complete FIL Method that assumes a 90 day consumption period and the FRMAC's Default Crop/Produce DRL method (dose from all radionuclides considered)
2. 0.37 µCi/m^2 Cs-137, Mature Crop Ingestion DRL calculated using the FDA DIL and the FRMAC's Default Crop/Produce DRL method (only dose from Cs-137 considered)
3. 0.29 µCi/m^2 Cs-137, Mature Crop Ingestion DRL calculated using the complete FIL Method that assumes a 365 day consumption period and the FRMAC's Default Crop/Produce DRL method (dose from all radionuclides considered)

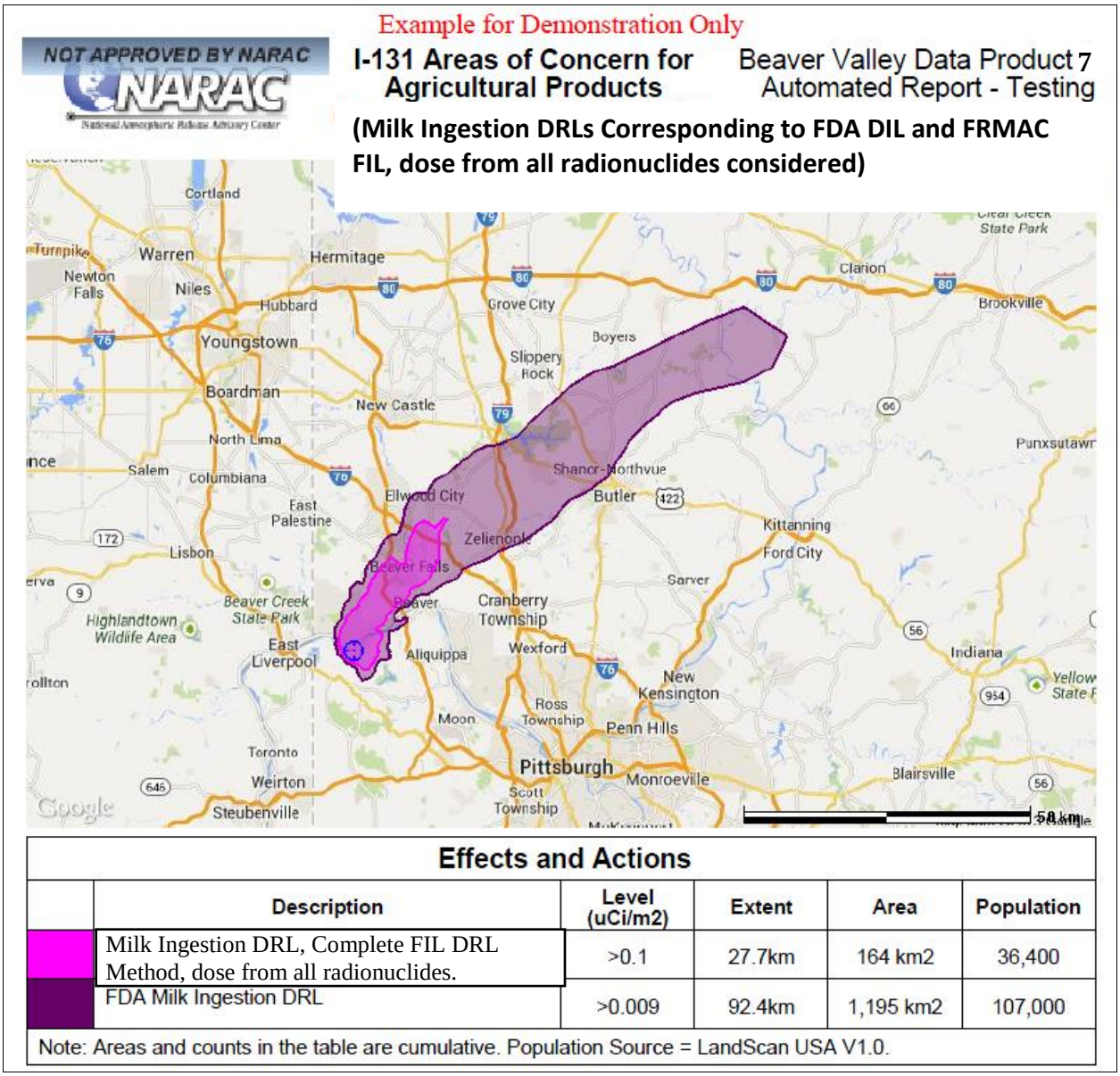


Long-Term Effects					
	Description	**Level (uCi/m2)**	**Extent**	**Area**	**Population**
	Cs-137 Crop DRL, FIL Method, 90 day consumption, dose from all radionuclides	>0.4	23.0km	78.9 km2	10,900
	Cs-137 Crop DRL, DIL Method, only Cs-137 dose	>0.4	23.1km	83.0 km2	12,100
	Cs-137 Crop DRL, FIL Method, 365 day consumption, dose from all radionuclides	>0.3	23.6km	93.3 km2	14,000
Note: Areas and counts in the table are cumulative. Population Source = LandScan USA V1.0.					

Figure 7: Comparison of Cs-137 Ingestion DRLs calculated using FDA's method and the complete FIL DRL method that considers all radionuclides in the source term.

Figure 8 shows two contours:

1. 0.009 µCi/m^2 I-131, Milk Ingestion DRL calculated using the FDA DIL and the FRMAC's Default Milk DRL method (only dose from I-131 considered)
2. 0.1 µCi/m^2 I-131, Milk Ingestion DRL calculated using the complete FIL Method that assumes a 60 day consumption period and the FRMAC's Default Milk DRL method



Effects and Actions

	Description	Level (uCi/m2)	Extent	Area	Population
	Milk Ingestion DRL, Complete FIL DRL Method, dose from all radionuclides.	>0.1	27.7km	164 km2	36,400
	FDA Milk Ingestion DRL	>0.009	92.4km	1,195 km2	107,000

Note: Areas and counts in the table are cumulative. Population Source = LandScan USA V1.0.

Figure 8: Comparison of I-131 Ingestion DRLs calculated using FDA's method and the complete FIL DRL method that considers all radionuclides in the source term.

Figure 7 shows that:

- The estimated impacted area (i.e., projected area where the crop may exceed the FDA PAG) calculated using FRMAC's default Crop/Produce DRL method and the FIL method, that considers the dose from all radionuclide contaminants and a 365 day consumption period, is only *slightly larger* than the impacted area estimated using the FDA DIL method that only considers the dose from Cs-137, and
- The estimated impacted area calculated using FIL method, that considers the dose from all radionuclide contaminants and a 90 day consumption period, is *slightly smaller* than the impacted area estimated using the FDA DIL method that only considers the dose from Cs-137.

Figure 8 shows that:

- The estimated impacted area (i.e., projected area where the milk may exceed the FDA PAG) calculated using FRMAC's default Milk DRL method and the FIL method, that considers the dose from all radionuclide contaminants and a 60 day consumption period, is *significantly smaller* than the impacted area estimated using the FDA DIL method that only considers the dose from Cs-137, and
- Because I-131 is the only radionuclide in the BV NPP mixture used in this analysis that delivers significant dose to the thyroid, the impacted area is not significantly changed by including only I-131 or all radionuclides in the assessment.

The following conclusions are drawn from Table 7 and Figures 7 and 8:

- Failure to account for all radionuclide contaminants can significantly underestimate the dose impacts,
- Failure to account for radioactive decay over the consumption period and any hold period can significantly over estimate the dose impacts from the contaminated food, especially when radionuclides with short half-lives are considered,
- Failure to account for radioactive decay over the consumption period and any hold period can significantly over estimate the size of the production area where food may exceed the FDA PAG, especially when radionuclides with short half-lives are considered,
- The FIL method provides more comprehensive and accurate assessments of the potential impacts of radiologically contaminated food.

4.0 POTENTIAL ADDITIONAL IMPROVEMENTS IN INGESTION ASSESSMENT MODELING

This section identifies additional inputs that may be updated to improve the accuracy of ingestion pathway assessments.

4.1 Consider Updating Dietary Intake Rates

The FDA's 1998 guidance uses dietary intake rates from the 1984 EPA reports (EPA 1984a, EPA 1984b), and this data is based upon data from the 1977-78 Nationwide Food Consumption Survey published by the USDA (USDA 1882, USDA 1983). An AWG-Focus Group is currently reviewing updated dietary intake data to determine if the dietary intakes rates used in FDA's 1998 guidance accurately reflect the current U.S. dietary habits. The dietary intake rate assumptions should then be updated, as appropriate.

4.2 Consider Updating Intake Period Assumptions

The 1998 EPA guidance assumes that for all radionuclides, except short-lived radionuclides, the contaminated food is consumed 365 day/year. This may be an overly conservative assumption in many cases because the contaminated food will likely be embargoed and not available for consumption, or the food may not be available for consumption because of a short shelf life. For example milk generally does not have a shelf life of 60 days, but we assume 60 and 365 day consumption periods when making DIL calculations for milk contaminated with I-131 and Cs-137, respectively.

More accurate assessments could be made with more realistic consumption period assumptions. Radiological assessors should work with regulators to consider more realistic consumption period estimates when assessing the radiological impacts of contaminated food.

4.3 Consider Modifying Intake Assumptions to Consider Category of Contaminated Food and Most Sensitive Age Group

Food pathway analyses should be able to consider the category of contaminated food, the appropriate age groups likely to consume the contaminated food and the appropriate intake rates. Overly conservative ingestion assessments result in some cases because the FDA assumes that 30% of the entire diet (most age groups and most radionuclides) or 100% of the entire diet (3-month and 1-yr old age groups for, I-131, I-133, Te-132 and Np-239) is contaminated food. For example if meat is contaminated with Np-239, does it make sense to enforce a DIL based on the 3-month old child that assumes the child's entire diet is contaminated meat? Radiological assessors should work with regulators to consider more realistic assumptions on which age group is likely to consume the contaminated food.

4.4 Consider Modifying Ingestion DRL Assumptions

All ingestion pathway assessment input variables and assumptions described above are germane to the calculation of the amount of contamination in the food (i.e. DIL) that would result in the food exceeding the FDA's recommended food PAGs. The Ingestion DRL calculation is also a very important calculation because it identifies the food production areas where the food may

exceed the FDA PAGs. The Ingestion DRL calculation requires numerous input variables and assumptions should be investigated to determine if they are appropriate or if they should be modified using event-specific inputs to improve ingestion pathway assessments. The FRMAC Assessment Manual (SNL 2012) specifies the defaults currently used in the Ingestion DRL calculations. A detailed analysis of the Ingestion DRL inputs is beyond the scope of this paper; however, the following key inputs are identified for future consideration.

- Crop Retention Factor – the fraction of the contamination that is assumed to be retained by the edible portion of the crop. The current CRFs do not distinguish between exposed and protected crops,
- Crop Yield - the mass of crop grown per area of land,
- Transfer Factor - the fraction of a radionuclide deposited on the growing medium that is transferred to the plant, milk or meat during the growing/production season, and
- Fraction of Diet Contaminated - the fraction of the animal's diet that is from contaminated feed or water.

5.0 CONCLUSION

The proposed FIL Method provides a more comprehensive and accurate method to perform ingestion pathway assessments. The FRMAC Assessment Working Group should approve the implementation of the FIL method as an alternative method to supplement the current default DIL Method recommended by the FDA. FRMAC personnel should work closely with the FDA representative on the Advisory Team to implement the FIL Method, as appropriate.

REFERENCES

EPA 1984a, Environmental Protection Agency. An Estimation of the Daily Food Intake Based on Data from the 1977-1978 USDA Nationwide Food Consumption Survey. Office of Radiation Programs. Washington, D.C.: EPA 520/1-84-015; 1984.

EPA 1984b, Environmental Protection Agency. An Estimation of the Daily Average Food Intake by Age and Sex for Use in Assessing the Radionuclide Intake of Individuals in the General Population. Office of Radiation Programs. Washington, D.C.: EPA 520/1-84-021; 1984.

FDA 1998, Accidental Radioactive Contamination of Human Foods and Animal Feeds: Recommendations for State and Local Agencies, U.S. Food and Drug Administration, Washington, DC, August 13, 1998.

ICRP 1989, International Commission on Radiological Protection. Age-dependent Doses to Members of the Public from Intake of Radionuclides. Oxford: Pergamon Press; ICRP Publication 56, Part 1; Ann. ICRP 20(2); 1989.

Kraus 2013a, Comparing FDA and ICRP 60 Ingestion DC.xlsx, Albuquerque, NM: Sandia National Laboratories; 2013.

Kraus 2013b, Compare FDA and Modified DIL calculations I-131 Milk.xlsx, Albuquerque, NM: Sandia National Laboratories; 2013.

Kraus 2013c, FIL calculations for FDA – FIL Comparison.xlsx, Albuquerque, NM: Sandia National Laboratories; 2013.

NRPB 1987, National Radiological Protection Board. Committed Doses to Selected Organs and Committed Effective Doses from Intakes of Radionuclides. Chilton, Didcot, Oxfordshire: NRPB Publication GS7; 1987.

SNL 2012, Sandia National Laboratories, FRMAC Assessment manual, Volume 1, Overview and Methods, Albuquerque, NM: Sandia National Laboratories; SAND2012-0888P; 2012.

USDA 1982, U. S. Department of Agriculture. Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion. Washington, D. C.: Human Nutrition Service; Home Economics Research Report No. 44; March 1982.

USDA 1983, U. S. Department of Agriculture. Food Intakes: Individuals in 49 States, Year 1977-1978. Washington D. C.: Human Nutrition Service; National Food Consumption Survey 1977-78; Report No. I-1; August 1983.

DISTRIBUTION

1	MS0791	B. Hunt	6631
1	MS0791	T. Kraus	6631
1	MS0791	T. Laiche	6631
1	MS0899	Technical Library	9536 (electronic copy)


Sandia National Laboratories