

(Unofficial)

Announcement of the Food and Drug Administration
Re: Auditing of Method, Equipment in Irradiation and Storage of Irradiated Food
under the Notification of Ministry of Public Health Re: Irradiated Food

To having criteria for consideration and auditing of food irradiation premises.

By the virtue of provision of Clause 7 of the Notification of Ministry of Public Health, Re: Irradiated Food dated 14th September B.E.2553 (2010) which has been issued by the virtue of provision of Section 5, Section 6 (7) and (10) of the Food Act B.E.2522 (1979), the Secretary-General of the Food and Drug Administration with an approval of the Food Committee has announced as follows:

Clause 1 Inspection of food irradiation premises under the Notification of Ministry of Public Health Re: Irradiated Food dated 14th September B.E.2553 (2010), the following forms and criteria shall be used:

- (1) Form Torsor. 7(53) for food irradiation premises inspection;
- (2) Form Torsor. 8(53) Criteria for consideration of results of food irradiation premises inspection.

This announcement shall come into force as from the day following date of its publication in the Government Gazette onwards.

Announced on the 27th October B.E. 2553 (2010)

(Signed) Pipat Yingseree

(Mr. Pipat Yingseree)

Secretary-General of Food and Drug Administration

(Published in the Government Gazette Vol. 127, Special Part 130 Ngor, dated 11th November 2010.)

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

Form food irradiation premises inspection

.....

Date..... time..... Mr, Mrs, Miss

Authorized officers under the provision of Section 43 of the Food Act B.E.2522 are ready to inspect together at food irradiation premise name.....

which having an operator/ licensee name.....

address of the food radiation premise at.....

Food production license/ Food production premise no.

Food categories applying/permitted

Purpose of inspection: Complement of permission power of production.....HP Number of workers.....

(as the case maybe) Monitoring others.....

At the time of inspections:

weight	Inspection items	Good 2	fair 1	improved 0	scores	remark
	1. Location, irradiation building, and design					
	1.1. Building location ad surroundings have the following description:					
0.2	1.1.1 No accumulation of non-use materials					
0.2	1.1.2 No accumulation of garbage.					
0.2	1.1.3 No heavy dust.					
0.2	1.1.4 No hazardous substances					
0.2	1.1.5 No byre or animal husbandry area					
0.2	1.1.6 No flooding and repugnant					
0.2	1.1.7 Having drained pipeline or ways outside building for drainage					
	1.2 Design of irradiation building have the following description					
0.3	1.2.1 Having a permission by the responsible government agency on the safety aspects. (license for possession of irradiation source; Office of Atomic Energy for Peace, License of factory establishing; Department of Industrial Works)					
0.2	1.2.2 having sufficient area for irradiation					

Signed (.....) applicants / licensee / representative

weight	Inspection items	Good 2	fair 1	improved 0	scores	remark	
0.2	1.2.3 Easy to maintenance, cleaning and convenient for operation						
0.2	1.2.4 Having sufficient light for operation						
0.2	1.2.5 Having suitable ventilation for operation						
0.5	1.2.6 Having measure to prevent animals and insects (Wire screen/plastic curtain)						
	1.3 Inside irradiation building						
0.3	1.3.1 Having room or area for storage of non irradiated food (clean, be able to prevent contamination, optimum temperature)						
0.3	1.3.2 Having room or area for storage of irradiated food (clean, be able to prevent contamination, optimum temperature)						
0.2	1.3.3 Rooms or areas for storage of irradiator and irradiation facilities (safety)						
0.2	1.3.4 Separated irradiation room						
0.3	1.3.5 Irradiation rooms or areas are in consequence of irradiation operation line						
0.5	1.3.6 Irradiation rooms or areas are separated from office, restrooms, and no accommodation for staff in the irradiation building						
0.2	1.3.7 No non-use or irrelevant materials in the irradiation building						
Topic 1					total scores =	10	Score Score (..... %)
					Actual score =		
weight	Inspection items	Good 2	fair 1	improved 0	scores	remark	
2. Radiation source and its facilities							
1.25	2.1 Compliance of ionizing radiation for food irradiation with regulation (Gamma ray, X ray, electrons)						
1.25	2.2 Design of radiation facilities provides an absorbed dose to food within achievable limits of objectives and complied with regulatory requirements.						
Topic 2					total score =	5	Scores Scores (..... %)
					Actual score =		

Signed (.....) applicants / licensee / representative

weight	Inspection items	Good 2	fair 1	improved 0	scores	remark
	3. Irradiation operation and control					
0.75	3.1 Foods intended for irradiation process shall be prepared under Good Manufacturing Practices in compliance with the MOPH notifications entitled “Production Processes, Production Equipments, and Food Storages” or “Minimum requirement on food hygiene” or “General Principles of Food Hygiene” as the case may be (food serial numbers)					
0.5	3.2 Transportation and storage of the food product prior to irradiation shall have preventive measures to prevent contamination. and hygiene (methods of transportation, clean storage area, integrity of packaging)					
0.75	3.3 The size and shape of packaging used for irradiation shall be designed appropriately for characteristics of food and characteristics of irradiation facilities. (document of dose mapping)					
	3.4 Irradiation					
1	3.4.1 Establish a clear statement for the purpose of irradiation (Application form for irradiation/food labels)					
1	3.4.2 Estimate the dose range to achieve the purpose of irradiation which appropriated with the food product intended for irradiation and complied with regulations.					
2 (M)	3.4.3 Test a plant commissioning to detect minimum and maximum absorbed points for the first time operation and whenever there is a change in radiation source. (documents of plant commissioning)					
2 (M)	3.4.4 Test a dose mapping for a particular food product or a group of food products for the first irradiation and whenever there is a change in loading configuration, weight, density, packaging of foods and radiation source (documents of dose mapping)					

Signed (.....) applicants / licensee / representative

weight	Inspection items	Good 2	fair 1	improved 0	scores	remark	
2 (M)	3.4.5 Control the following parameters that influence on absorbed dose to ensure that food exposed to dose achieved the objective of irradiation in each cycle, such as						
	3.4.5.1 Correct position of radiation source						
	3.4.5.2 Time for irradiation						
	3.4.5.3 Strength of radiation source						
	3.4.5.4 Absorbed dose						
	3.4.5.5 Order of loading configuration and food product density						
	3.4.5.6 Having record						
	3.5 Product identification						
0.75	3.5.1 Giving a code number to identify the packages at each step in its path through the irradiation process						
0.75	3.5.2 Recording all relevant parameters regarding to the code or number of product (date, time, strength of radiation source, minimum and maximum absorbed dose, temperature).						
	3.6 Post-Irradiation Handling						
1.25	3.6.1 Having appropriate system to separate irradiated foods from non-irradiated foods.						
0.75	3.6.2 Having appropriate inspection and storage of irradiated foods as well as the packaging of irradiated food must be complete appearance.						
1	3.6.3 Having adequate control of product and inventory control system to ensure that specific consignments of food products be traced back both to the irradiation facility and the food manufactory prior to irradiation.						
0.5	3.6.4 Having appropriate transportation procedures to prevent contamination of irradiated food. (transportation system, clean packaging)						
topic 3					total scores =	30	<i>scores</i>
					Actual score =		<i>scores</i> <i>(..... %)</i>

Signed (.....) applicants / licensee / representative

weight	Inspection items	Good 2	fair 1	improved 0	scores	remark	
4. Dosimetry and control							
2	4.1 Selection an appropriate dosimetry system that suitable for the irradiation objectives and relevant factorsthe system's use (dosimetry system and complimentary document.)						
2.5	4.2 Carrying out measurement of a dose distribution. (Report of dose distribution)						
3 (M)	4.3 Carrying out measurement of the absorbed dose of food product in the production lot. (report of absorbed dose at minimum and maximum point).						
2.5	4.4 Planning and calibration of dosimetry system for radiation processing shall be traceable to national or international standards at least once a year at appropriate time.						
topic 4					total scores =	20	<i>scores</i>
					Actual scores =		<i>scores (..... %)</i>
weight	Inspection items	Good 2	fair 1	improved 0	scores	remark	
5 Record and report							
	5.1 Records of product details as follows:						
0.75	5.1.1 Weight, food density, and quantity of products that intended for the irradiation process at each production lot.						
0.5	5.1.2 Type of packaging materials used for irradiation.						
0.25	5.1.3 Name and address of food manufacturers in each irradiation lot						
0.25	5.1.4 Product code number or lot number of each production lot						
	5.2 Records of data and control of parameters affected on irradiation process as follows:						
0.25	5.2.1 Strength of radiation source						
0.25	5.2.2 Type of irradiation source, dose range intended to use, and the arrangement of products in the package						
0.25	5.2.3 Date of irradiation and purpose of irradiation						
0.75	5.2.4 Minimum and maximum absorbed dose including type of dosimeters						
0.25	5.2.5 Details of dosimetry system calibration						

Signed (.....) applicants / licensee / representative

weight	Inspection items	Good 2	fair 1	improved 0	scores	remark
0.5	5.2.6 The position of dosimeters, radiation dose, and dosimetry results					
0.25	5.2.7 Results of test samples to confirm the position of dosimeters on food products.					
0.25	5.2.8 Method (including instruments and frequency of measurement) for dosimetry process and validation tests					
0.75	5.3 Reports of dosimetry result.					
0.75	5.4 Records of machine and equipment maintenance system					
0.75	5.5 Records or reports of staffs' trainings					
0.25	5.6 Records of transportation and their conditions					
0.25	5.7 Records of all relevant documents verification.					
0.25	5.8 Records of report relevant to irradiation are kept at the facility with good system and not less than 3 years					
topic 5					total scores = 15	<i>scores scores (..... %)</i>
					Actual scores =	
weight	Inspection items	Good 2	fair 1	improved 0	scores	remark
6. Sanitation						
0.25	6.1 Water used for general cleaning has suitable quality for working purpose					
0.5	6.2 Appropriate and effective drainage					
0.25	6.3 Garbage bin with lids in appropriate and adequate manner					
0.25	6.4 Having appropriate elimination system.					
0.5	6.5 Adequate and sanitary toilets, hand wash basin with fully facilities to wash hand for staff					
0.75	6.6 Having appropriate measures for animals and insects elimination in irradiation area (pest control).					
Topic 6					total scores = 5	<i>scores scores (..... %)</i>
					Actual scores =	

Signed (.....) applicants / licensee / representative

weight	Inspection items	Good 2	fair 1	improved 0	scores	remark	
7. Cleaning and maintenance							
0.5	7.1 Irradiation building is clean and having procedure or measure for regularly cleaning (clean, procedure, frequency)						
0.5	7.2 Irradiation building maintain in good condition regularly						
0.5	7.3 Tools, equipments and irradiation facilities used for irradiation are kept in clean condition						
0.5	7.4 Tools, equipments, irradiation facilities used for irradiation process shall have maintenance program and shall operate and inspected to maintain in good condition for efficient uses.						
0.5	7.5 Having separated area for keeping Chemical for washing or sanitizing and clearly identified.						
topic 7					total scores =	5	<i>scores scores (..... %)</i>
					Actual scores =		
weight	Inspection items	Good 2	fair 1	improved 0	scores	remark	
8. Personnel and personal hygiene							
0.75	8.1 Staffs in irradiation building shall not be infected from contagious disease or repugnant disease as prescribed in the Ministerial Regulation No.1 (B.E. 2522) (1979)						
	8.2 Operators which have direct contact to food must be as the followings:						
0.25	8.2.1 Wear clean clothes outer garment or apron shall be clean. (if any)						
0.5	8.2.2 Having measures of a personal hygiene as necessary						
	8.3 The operational staffs of irradiation process shall be trained as the followings:						
0.75	8.3.1 Hygiene Training for workers as appropriate (at least once a year)						
1.25 (M)	8.3.2 Worker training for skillful control of irradiation (documents of attended and passed training)						
1.25 (M)	8.3.3 Worker training for skillful dosimetry measurement (documents of passed training)						
0.25	8.4 Procedures or instruction for person not relevant to production enter into building when necessary						
Topic 8					total scores=	10	<i>scores scores (..... %)</i>
					Actual scores=		

Signed (.....) applicants / licensee / representative

Inspection summary

1. Total scores (every topic) = 100 marks

Total actual scores (every topic) =..... marks (.....%)

2. Passed the criteria

Not passed the criteria in the following topics

Topic 1 Topic 2 Topic 3 Topic 4

Topic 5 Topic 6 Topic 7 Topic 8

Major defect found in the area of plant commissioning for detection of minimum and maximum points every time at the first time operation and whenever having a change in radiation source (topic 3.4.3)

Major defect found in the area of dose mapping in all kinds of food products or food product categories at first time of irradiation and whenever changes of arrangement, weight, density o food, packaging including change of radiation (topic 3.4.4)

Major defect found in the area of control and record of all parameters that influence on absorbed dose to ensure that the intended purpose of irradiation is achieved throughout the production lot as follows : position of radiation source ,time, strength, absorbed dose, order of loading configuration, food product density and records (topic 3.4.5)

Major defect found in the area of absorbed dose measurement at each point of food products in each production lot (item 4.3)

Major defect found in the area of worker training for skillful control of irradiation (topic 8.3.2)

Major defect found in the area of worker training for skillful dosimetry measurement (topic 8.3.3)

Other defects found. as follows.....

.....

.....

.....

.....

.....

.....

.....

Signed (.....) applicants / licensee / representative

3. Evaluation results

An overview of evaluation.....

.....

.....

.....

.....

.....

.....

Change in internal organization.....

.....

.....

.....

.....

Implementation of criteria and condition in certification including presentation /reference of certificate certification mark and certified management system mark (if any)

.....

.....

.....

.....

Action taken for those defects found in the last evaluation (if any)

.....

.....

.....

.....

Strength.....

.....

.....

.....

.....

Signed (.....) applicants / licensee / representative

Remarks and opportunity for improvement.....

.....
.....
.....
.....
.....
.....
.....
.....

Comments of audit team

- Agree to propose for certification (permit)/maintain/renew for certification(license)
- Others (specify).....

.....
.....
.....
.....
.....

4. At the time of the inspection of this premises by authorized officers, no any loss or damage has been made to property of applicant/licensees, after listening and agreed to truly certified by signing in front of the authorized officers at the end of this .

Remark expect to deliver correction to the officers within date.....

Signed applicants / licensee / representative
(.....)

(signed).....authorized officer

(signed).....authorized officer

(signed).....authorized officer

(signed).....authorized officer

Criteria for consideration of result of food irradiation premises inspection

1. To make decision there are 3 levels for giving scores as follows:

level	definition	Evaluated scores
Good	Complied with those criteria specified in the annex of the Notification of Ministry of Public Health, Re: Irradiated foods.	2
Fair	Complied with those criteria specified in the annex of the Notification of Ministry of Public Health, Re: Irradiated foods but still some acceptable minor defects are found because of having control or prevention measures or such defects does not directly impact to food produced.	1
Improve	Not complied with those criteria specified in the annex of the Notification of Ministry of Public Health, Re: Irradiated foods.	0

2. Score calculation

2.1 Method to calculate in each topic are as follows:

Actual scores = weight of scores in each topic x evaluated scores

Percentage of actual scores in each topic = $\frac{\text{Total actual scores} \times 100}{\text{Total scores in each topic}}$

2.2 Remark column in Checklist is for an auditor be able to put down data and remarkable items especially for fair and improved items remark of scores given shall be written down the reason and when all 8 topics have been finished, this remark column will help to recall and fairly support scoring including it will be information for the next surveillance. Beside this data from remark column can be used for scoring or suggestion to business operator or appreciate the establishment that make a good feeling of officers as advisor or consultant instead of authorized inspectors to undertake legal operation.

Example of calculation

weight	Inspected items	good 2	fair 1	improve 0	Actual score	Remark
	3. Irradiation operation and control					
0.75	3.1 Foods intended for irradiation process shall be prepared under Good Manufacturing Practices in compliance with the MOPH notifications entitled “Production Processes, Production Equipments, and Food Storages” or “Minimum requirement on food hygiene” or “General Principles of Food Hygiene” as the case may be (food serial numbers)	/			(2x0.75) = 1.5	
0.5	3.2 Transportation and storage of the food product prior to irradiation shall have preventive measures to prevent contamination. and hygiene (methods of transportation, clean storage area, integrity of packaging)	/			(2x0.5) = 1	
0.75	3.3 The size and shape of packaging used for irradiation shall be designed appropriately for characteristics of food and characteristics of irradiation facilities. (document of dose mapping)		/		(1x0.75) = 0.75	
	3.4 Irradiation					
1	3.4.1 Establish a clear statement for the purpose of irradiation (Application form for irradiation/food labels)	/			(2x1) = 2	
1	3.4.2 Estimate the dose range to achieve the purpose of irradiation which appropriated with the food product intended for irradiation and complied with regulations.	/			(2x1) = 2	
2 (M)	3.4.3 Test a plant commissioning to detect minimum and maximum absorbed points for the first time operation and whenever there is a change in radiation source. (documents of plant commissioning)	/			(2x2) = 4	
2 (M)	3.4.4 Test a dose mapping for a particular food product or a group of food products for the first irradiation and whenever there is a change in loading configuration, weight, density, packaging of foods and radiation source documents of dose mapping)	/			(2x2) = 4	
2 (M)	3.4.5 Control the following parameters that influence on absorbed dose to ensure that food exposed to dose achieved the objective of irradiation in each cycle , such	/			(2x2) = 4	
	3.4.5.1 Correct position of radiation source					
	3.4.5.2 Time for irradiation					
	3.4.5.3 Strength of radiation source					
	3.4.5.4 Absorbed dose					
	3.4.5.5 Order of loading configuration and food product density					
	3.4.5.6 Having record					

weight	Inspected items	good 2	fair 1	improve 0	Actual score	Remark
	3.5 Product identification					
0.75	3.5.1 Giving a code number to identify the packages at each step in its path through the irradiation process			/	(0x0.75)=0	
0.75	3.5.2 Recording all relevant parameters regarding to the code or number of product (date, time, strength of radiation source, minimum and maximum absorbed dose, temperature).		/		(1x0.75)=0.75	
	3.6 Post-Irradiation Handling					
	3.6.1 Having appropriate system to separate irradiated foods from non-irradiated foods.	/			(2x1.25)=2.5	
0.75	3.6.2 Having appropriate inspection and storage of irradiated foods as well as the packaging of irradiated food must be complete appearance.		/		(1x0.75)=0.75	
1	3.6.3 Having adequate control of product and inventory control system to ensure that specific consignments of food products be traced back both to the irradiation facility and the food manufactory prior to irradiation.	/			(2x1)=2	
0.5	3.6.4 Having appropriate transportation procedures to prevent contamination of irradiated food. (transportation system, clean packaging)	/			(2x0.5)=1	
topic 3 total scores =					30	<i>Scores</i>
Actual score =					26.25	<i>scores (87.5%)</i>

3. Major defect means risky defect that may make irradiation of food unable to achieve the objective and contamination may happen and not safe for consumer as follows:

3.1 No testing of a plant commissioning to detect the minimum and maximum point for the first operation and whenever there is a change in radiation source (topic 3.4.3).

3.2 No testing a dose mapping for a particular food product or a group of food products for the first irradiation and whenever there is a change in loading configuration, weight, density, packaging of foods and radiation source (topic 3.4.4).

3.3 No Control and record of all parameters that influence on absorbed dose, such as: position of radiation source, time, strength, absorbed dose, order of loading configuration, food product density to ensure that the intended purpose of irradiation is achieved throughout the production lot (topic 3.4.5).

3.4 No measurement of the absorbed dose of food product in the production lot (topic 4.3).

3.5 No skillful training of the operation of irradiator and irradiation facilities for responsible staffs (topic 8.3.2).

3.6 No skillful training of irradiation process control and dosimetry measurement for responsible staffs.

3.7 Other defects which audit team considered to be risk that may cause unsafe food to consumer.

4. Acceptance of audit passed, total scores of each topic and total actual scores shall not be less than 80% and major defects shall not be found therefore to consider as complied with law.