ATOMIC ENERGY (CONTROL OF IRRADIATION OF FOOD) RULES, 1996

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ATOMIC ENERGY (CONTROL OF IRRADIATION OF FOOD) RULES, 1996

G.S.R. 254, dated 29th March, 1996.1 In exercise of the powers conferred by Section 30 read with Section 14 and 17 of the Atomic Energy Act, 1962 (33 of 1962) and in supersession of the Atomic Energy (Control of Irradiation of Food) Rules, 1990, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules, namely :

1. Short title and commencement :-

(1) The resin bed in the water conditioning system shall be daily checked with a radiation survey instrument. The survey instrument should be sensitive enough to detect minimum radioactivity of 2000 Eq. in the resin bed. In the event of detection of activity above this level, water circulation system shall be stopped and irradiator shall be withdrawn from service.

(2) In addition the pool water shall be checked for contamination by using an on-line radiation monitor on a pool water circulating system.

(3) The detection of above normal radiation levels must activate an alarm. Activation of alarm must automatically cause the water purification system to shut off.

1 \Standards of packaging material

. .

(1) Where packing is essential to prevent post-treatment recontamination, the food should be packed before treatment.

(2) Package size especially with bulk packs should be such that they can be handled efficiently thereby avoiding excessive delays and temperature abuse.

(3) The choice of the packing material and the nature of the container for specific food is usually determined by the purpose they are to serve and storage conditions, such as prevention of moisture loss or moisture uptake, to provide an atmosphere devoid of air, or to avoid mechanical damage to food.

(4) Sterilized food must have containers which prevent access to bacteria or other micro-organisms.

1 \The overall average absorbed dose

. . It can be asumed for the purpose of the determination of the wholesomeness of food treated with an overall average dose of 10 kGy or less, that all radiation chemical effects in that particular dose range are proportional to dose. The overall average dose, D, is defined by the following integral over the total volume of the goods. D = J (x, y, z), d(x, y, z).dv M where M = the total mass of the treated sample l = the local density at the point (x, y, z) d = the local absorbed dose at the point (x, y, z) dv = dx dy dz the infinitesimal volume element which in real case is represented by the volume fractions. The overall average absorbed dose can be determined directly by homogeneous products or for bulk goods of homogeneous bulk density by distributing an adequate number of dose meters strategically and at random throughout the volume of the goods. From the dose distribution

determined in this manner an average can be calculated which is the overall average absorbed dose. If the shape of the dose distribution curve through the product is well determined the positions of minimum and maximum dose are known. Measurements of the distribution of dose in these two positions in a series of samples of the product can be used to give an estimate of the overall average dose. In some cases the mean value of the average values of the minimum (Dmin) and maximum (Dmax) dose will be a good estimate of the overall average dose, i.e., in these cases. Dmax + Dmin over average dose =

1 \.

The complete design drawings of the facility indicating the details of the shielding, surrounding the source, wall thickness, labyrinth access, openings voids, reinforcements, mechanical and electrical safety system, ventilation, fire protection systems.)

1 \Short title and commencement

. .

(1) These rules may be called the Atomic Energy (Control of Irradiation of Food) Rules, 1996.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions :-
Swipe test using a moist paper of 100 square centimeter area shall be conducted weekly on the closest accessible surface near the source in storage condition. Activity on the sample shall be counted by a radiation survey instrument with a minimum detection capability of 2000 Bq on swipe sample. In the event of detection of activity above this level, irradiator shall be withdrawn from service.

2 \Rigid Containers

. .

(1) Primary rigid container used for irradiated food is metal can, Steel containers, tin-plated and lined with appropriate enamel such as polybutadiene or epoxy-phenolic have found to be satisfactory.

(2) Secondary rigid containers made of wood, fibre board or glass are also used.

2 \Effective and limiting dose values

. .

(1) Some effective treatment e.g., the elimination of harmful microorganisms or a particular shelflife extension or a disinfestation

requires a minimum absorbed dose. For other applications too high an absorbed dose may cause undesirable effects or an impairment of the quality of the product.

(2) The design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process. In some low dose applications it will be possible within the terms of paragraph 4 on Good Radiation Processing Practice to allow a ratio of maximum to minimum dose of greater than 3.

(3) With regards to the maximum dose value under acceptable wholesomeness considerations and because of the statistical distribution of the dose of mass fraction of product of a least 97.5% should receive and absorbed dose of less than 15 kGy when the overall average dose is 10 kGy.

2 \.

The environs of the facility including residential complexes, occupancy within 50 m radius of the facility, geology of the location, water table, soil characteristics, stismicity.

2 \Definitions

. . In these rules unless the context otherwise requires :

(a) "Act" means the Atomic Energy Act, 1962 (33 of 1962),

(b) "applicant" means the person making an application for the grant of licence;

(c) "Certificate of approval" means the certificate of approval granted by the competent authority for operating an irradiation facility in accordance with rule 5.

(d) "Certificate of Irradiation" means the certificate of irradiation issued by the licensee under rule 12 ;

(e) "Certificate of release" means certificate of release issued by the licensing authority under rule 25 ;

(f) "Competent authority" means such officer or authority directed by the Central Government under Section 27 of the Act to exercise the powers or discharge the duties under these rules ;

(g) "dosimetry" means the method to measure the absorbed dose of radiation by the food.

(h) "food" means article of food referred to in column 2 of Sch. 1 ;

(i) "Form" means the Form annexed to these rules ;

(j) "inspection report" means the inspection report referred to in rule 10;

(k) "irradiation facility" means any facility which is capable of being utilised for the treatment of food by radiation ;

(l) "irradiated food" means articles of food subjected to radiation by :

(i) Gamma rays:

(ii) X-rays generated from machine sources operated at or below an energy level of 5 million electron volts ;

(iii) Sub-atomic particles, namely electrons generated from machine sources operated at or below an energy level of 10 Million electron volts, to dose levels as specified in Sch

(m) "licence" means licence for operating an irradiation facility issued under rule 4;

(n) "licensee" means the person named in the licence in whose favour the licence is issued.

(o) "Licensing authority" means the Central Government or such officer or authority directed by the Central Government under Section 27 of the Act to grant license under Section 14 of the Act ;

(p) "operational limits" means limits specified by the competent authority on the level of radiation to workers and members of the public and on the level of radioactive contamination from the radioactive sources used in the irradiation facility ;

(q) "operator" means any person, appointed as such by the licensee and who shall have the qualification and other requirements as specified in paragraph 2 of Sch. II;

(r) "Quality Control Officer" means any person appoinded as such by the licensee who shall have the qualification and other requirements as specified in paragraph 3 of Sch. II ;

(s) "Radiological Safety Officer" means any person appointed as such by the licensee who have the qualification and other requirements as specified in paragraph I of Sch. II ;

(f) "Schedule" means "Schedule annexed to these rules.

3. Conditions precedent for the issue of a licence :-
Flexible plastic containers because of their low density are highly suitable for packing irradiated food. Films over 76 cm. thick are satisfactory for preservation of irradiated products. In case laminates are used their performance should satisfy the following criteria :

(i) The films are not changed adversely :

(a) in their protective characteristics (e.g., seal stability, permeability, etc.),

(b) by radiation induced changes in the food,

(c) causing transmission of toxic or potentially toxic, and substances to the food.

(ii) Polymeric films recommended for use upto 10 kGy are :

(a) Nitrocellulose or vinylidene coated cellophane ;

(b) Wax coated paper board ;

(c) Glassine paper;

(d) Polystyrene;

(e) Rubber hydrochloride;

(f) Vinylidiene chloride vinyl chloride ;

(g) Polyethylene;

(h) Polyethylene terephthalate;

(i) Nylon 6;

(j) Nylon 11 ;

(k) Vinyl chloride vinyl acetate ;

(l) Vegetable parchment.

3 \Routine dosimetry

. . - Measurements of the dose in a reference position can be made occasionally throughout the process. The association between the dose in the reference position and the overall average dose must be known. These measurements should be used to ensure the correct operation of the process. A recognized and calibrated system of dosimetry should be used. A complete record of all dosimetry measurements

including calibration must be kept.

3 \.

Complete description of the radiation source, address of the supplier and the operating condition of the source such as source drive system.

3 \Conditions precedent for the issue of a licence

. . No licence for operating an irradiation facility shall be granted, unless the applicant obtains a certificate of approval from the competent authority, after submitting documents as specified in Sch. III to the effect that the facility is in conformity with the general conditions for design, operation and efficiency criteria as specified in Sch. IV.

4. Licence :-

(1) Inventory control. For irradiated foods, whether prepacked or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the date(s) of treatment and lot identification.

(2) Prepacked foods intended for direct consumption. The labelling of prepackaged irradiated foods shall be in accordance with the relevant provision given in Prevention of Food Adulteration Rules.

(3) Food in bulk containers. The declaration of the fact of irradition shall be made clear on the relevant shipping documents.

4 \Good radiation processing practice

. .

(1) The design of the irradiator should have the facility to optimize the dose uniformity ratio to ensure appropriate dose rates and where necessary to permit temperature control during irradiation (e.g., for treatment of frozen food) and also control of atmosphere.

(2) Care must be exercised to minimize mechanical damage to the product during transport, irradiation and storage and to use irraditor to its maximum efficiency.

(3) Where the food to be irradiated is subjected to special standards for hygiene or temperature, control, the facility must permit compliance with these standards.

4 \Licence

. .

(1) An application for a licence shall be made to the licensing

authority in Form I and shall be accompanied by :

(a) a certificate of approval :

(b) fee of rupees five hundred payable in the form of a bank draft drawn in favour of the licensing authority.

(2) If the licensing authority is satisfied that the applicant is capable of operating an irradiation facility in accordance with these rules, it shall issue a licence in Form IV.

(3) If the licensing authority is satisfied that the applicant is not capable of operating an irradiation facility in accordance with these rules, it may, after giving the applicant reasonable opportunity of being heard against the proposed refusal of licence, by order setting out the reasons therein, refuse to grant the licence.

(4) Every order refusing to grant the licence sub-rule (3) shall be communicated to the applicant, by sending a copy of the order by registered post to the address given in the application.

5. Certificate of approval :-

(1) Except for foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect reinfestation, foods irradiated in accordance with 2 and 3 of this standard shall not be re-irradiated.

(2) For the purpose of this standard food is not considered as having re-irradiated when

(a) the food prepared from materials which have been irradiated at low levels e.g., about I kGy, is irradiated for another technological purpose.

(b) the food containing less than 5% of irradiated ingredient, is irradiated, or when

(c) the full dose of ionizing radiation required to achieve the desired effect is applied to the food is more than one instalment as part of processing for a specific technological purpose.

(3) The cumulative overall average dose absorbed should not exceed 10 kGy as a result of re-irradiation.

5 \Certificate of approval

. .

(1) An application for a certificate of approval shall be made to the competent authority in Form III.

(2) If the competent authority is satisfied that the applicant satisfies the requirements as specified in Sch. III and IV, it shall grant a certificate of approval in Form II.

(3) If the competent authority is satisfied that the applicant does not satisfy the requirements as specified in Sch III and IV, it may , after giving the applicant a reasonable opportunity of being heard against the proposed refusal of the certificate of approval, by order, setting out the reasons therein, refuse to grant the certificate of approval.

(4) Every order refusing to grant the certificate of approval under sub-rule (3), shall be communicated to the applicant by sending a copy of the order by registered post to the address given in the application.

6. Power to suspend the certificate of approval :-

(1) If the competent authority is satisfied, on the Basis of the inspection report that any irradiation facility has ceased to conform to the safely and efficiency criteria as specified in Schedule IV ; it may for reasons to be recorded in writing, make and order suspending the certificate of approval and call upon .the licensee to rectify the defects mentioned therein within a period of thirty days from the date of receipt of the order.

(2) The order of the competent authority made under sub-rule (1) along with the copy of the inspection report shall be communicated to the licensee who shall on receipt of the same, cease to operate the irradiation facility until he suspension of the certificate of approval is revoked under sub-rule (5).

(3) The competent authority shall transmit copies of the order and inspection report referred to in sub-rule (2) to the licensing authority.

(4) The competent authority shall enter in the certificate of approval the particulars of inspection.

(5) Where the competent authority is satisfied that pursuant to the order made under sub-rule (1) the licensee has rectified the defects mentioned therein, it may revoke the suspension of the certificate of approval and communicate in writing the decision to the

licensee.

(6) If the defects mentioned in the order are not rectified by the licensee within the period mentioned therein, the competent authority shall report the matter to the licensing authority for necessary action.

(7) Any person aggrieved by the order of suspension of certificate of approval by the competent authority may within a period of fifteen days from the receipt of the communication of such suspension prefer an appeal to the Atomic Energy Commission.

7. Power to suspend the Licence :-

(1) If the licensing authority is satisfied, on the basis of the inspection report that the licensee has failed to ensure that the irradiation facility under his control conforms to the safety and efficiency criteria specified in Sch. IV, it may for reasons to be recorded in writing make an order suspending the licence and call upon the licensee to rectify the defects mentioned therein within a period of thirty days from the date of receipt of the order.

(2) The period of thirty days stipulated under sub-rule (1) of rule 6 and rule 7 may be condoned by the licensing authority after having satisfied himself with the fact that the licensee in not able to rectify the defects for reasons beyond his control within the stipulated period of thirty days.

(3) The order made by the licensing authority under sub-rule (1) along with the copy of the inspection report shall be communicated to the licensee, who shall on receipt of the same, cease to operate the irradiation facility until the suspension of the licence is revoked.

(4) Where the licensing authority is satisfied that pursuant to the order made under sub-rule (1), the licensee has rectified the defects mentioned therein it may revoke the suspension of the licence and communicate the decision to the licensee.

(5) Any person aggrieved by the order of suspension or revocation of a licence by the licensing authority may within a period of fifteen days from the receipt of the communication of such suspension or revocation prefer an appeal to the Central Government.

8. Revocation of licence :-

Notwithstanding anything contained in rule 4, the licensing authority may after giving the licensee a reasonable opportunity of

being heard, by order setting out the reasons therein in writing revoke any licence or modify the terms and conditions of any licence on any of the following grounds, namely :

(1) Where the certificate of approval has been suspended and the competent authority has reported that the licensee has not rectified the defects mentioned in the order of suspension within the period stipulated therein; or

(2) Where the licence has been suspended and the licensee has not rectified the defects mentioned in the order of suspension within the period stipulated therein; or

(3) Where in the opinion of the licensing authority, it is necessary to do so, in order to ensure safety of persons whosoever may suffer any injury because of any negligence in the process of irradiation.

9. Conditions for irradiation of food :-

(1) The licensee shall not undertake irradiation of any food unless in his opinion such irradiation is necessary for its preservation, protection against parasites or improvement of its hygienic or technological quality.

(2) the licensee shall ensure that :

(a) the quality Control Officer has satisfied himself that the food to be irradiated is of good quality.

(b) in the case of packaged products, the packing material conforms to the standards specified in Sch. VII.

(c) the irradiated food is readily identified so as to prevent it from being subjected to subsequent irradiation.

(d) the dose limit, radiation source and irradiation conforms to the conditions specified in Sch. I and V.

(e) the irradiation facility is operated only by the operator.

10. Period Inspection of facilities :-

(1) The competent authority or any person authorised by him in this behalf shall undertake inspection of the irradiation facility at least twice in a year but the maximum gap between two inspections shall not exceed 8 months.

(2) The particulars of the inspection shall be recorded by an entry

on the certificate of approval.

(3) A copy each of the inspection report shall be forwarded to the licensee and to the licensing authority.

11. Record of food irradiation :-

(1) The licensee shall maintain, for each source of radiation used, a record in Form V indicating for each batch of food subject to radiation treatment:

(a) the serial number of the batch ;

(b) the date of irradiation;

(c) the nature and the quality or irradiated food and the batch number;

(d) the type of packaging used during the radiation treatment in the case of packaged products.

(e) the control and measurement performed during the treatment, particularly as regards the minimum and maximum limits of radiation dose;

(f) where appropriate, all supplementary information required by the specific irradiation conditions provided for in Sch. V;

(g) any incidents and anomalies observed during the irradiation treatment.

(2) The record shall contain the names and address of the operators and the quality control officer and the identification number of the irradiation facility.

(3) The licensee shall retain the records for a period of five years.

(4) The licensee shall maintain the records of standard model for the food irradiation in respect of each batch of food as specified in Form V.

12. Certificate of irradiation :-

(1) The licensee shall, on the basis of the data entered in the record of irradiated food, issue a certificate of irradiation for every batch of food item which has undergone irradiation in his facility.

(2) A copy of the certificate of irradiation shall be maintained by the licensee.

13. Irradiation voucher :-

The licensee shall issue to the person from whom an order for the irradiation of food has been received, an irradiation voucher for each batch of food containing the following particulars, namely :-

(1) the indentification number of the irradiation facility together with the names and adresses of the operator and quality control officer;

(2) the nature and quality of the batch of irradiated food and also the purpose of the irradiation;

(3) the date of the radiation treatment;

(4) the radiation source used and specific dose of radiation;

(5) the serial number of the batch which has been subjected to the treatment which number must correspond to the information in the irradiation record;

(6) date and signature of the licensee.

14. Maintenance of log books :-

Every licensee shall maintain and make available to any person duly authorised by the competent authority for inspection, a log book containing the following particulars, namely :

(1) description of the facility ;

(2) source details;

(3) the name of supplier of the source and his address ;

(4) the identity of Radiological Safety Officer (RSO).

15. Control of irradiation facility :-

(1) The competent authority or any person authorised by him in this behalf shall undertake verification to ensure that the operation of the facility and the use of radiation treatment procedures conform to the general and specific conditions as specified in Sch. IV.

(2) The licensee shall provide all reasonable facilities to the competent authority or any person authorised by him, to carry out inspection and measurement procedures as may be necessary.

16. Powers and duties of person authorised to inspect :-

(1) The competent authority or any person authorised by him in this behalf shall :

(a) have the right of access :

(i) to any place which is used for irradiation of food or for storage of food which has been or has to be irradiated :

(ii) to all documents relating to the irradiation facility the batches of food which have been or are to be irradiated, a certificate of approval, the copies of the inspection report, order of suspension, modification or revocation of licence, food irradiation records and the documents relating to purchase and sale accompanying the batches of food.

(b) to check the performance of the irradiation unit and measure the dosage to which the food is subject to;

17. Radiological Safety Officer :-

The qualifications for Radiological Safety Officer are given in Sch. II. No person shall be appointed as a Radiological Safety Officer unless such person:

(1) possesses a certificate towards his qualification by an institution or authority approved by the competent authority.

(2) is familiar with the operating and emergency procedures of the irradiation unit and has demonstrated his understanding thereof to the satisfaction of the competent authority.

(3) is familiar with the rules, notification and orders applicable to the irradiation facility and has demonstrated his understanding thereof to the satisfaction of the competent authority.

(4) has demonstrated to the satisfaction of the Competent Authority competence to use the irradiation facility and the radiation instruments to be used in his assignment.

18. Duties of Radiological Safety Officer :-

The Radiological Safety Officer shall

(1) instruct the radiation workers under his charge on the hazards of radiation and on suitable safety measures and work practices aimed at minimizing exposure to radiation;

(2) take all necessary steps aimed at ensuring that the operational limits as specified in Sch. VIII are not exceeded;

(3) carry out leakage tests as specified by the competent authority in Sch. IX and test of safety related systems;

(4) investigate and initiate prompt and suitable remedial measures in respect of any situation that could result in radiation hazard:

(5) ensure that reports on all hazardous situation along with details of any immediate remedial measures that may have been initiated, are made available immediately to his employer;

(6) assist the licensee in the safe disposal of decayed radioactive sources in the manners approved by the competent authority.

19. Monitoring of personnel :-
The licensee shall ensure that :

(1) every person entering the irradiation facility wears separate personnel monitoring device provide by him.

(2) such personnel monitoring devices are processed by an agency approved by the competent authority.

(3) investigation reports regarding all excessive exposures are forwarded to the competent authority.

(4) the workers exposed to radiation have been medically examined as specified by the competent authority.

20. Operating procedures :-
The licensee shall prepare a detailed operating procedure based on the manufacturer's manual which shall inter alias provide that :

(1) the irradiation facility shall be operated only in such a way that no person is likely to be exposed to radiation doses in excess of the operational limits notified by the competent authority.

(2) it shall be impossible to resume operation of irradiation facility after the return of the source to the fully shielded position without complying with the requirements such as interlocked controls for personnel access, radiation room lock-up sequence and source exposing operations.

(3) a single multipurpose key which is to operate the control console, to gain access to the radiation room and to activate safety related interlocks is available.

(4) the procedures and occasions for conducting radiation surveys and contamination tests are devised.

(5) the procedures for locking and the use of facility are available.

(6) monitoring of the personnel and the use of area monitoring equipment is made mandatory.

(7) transportation of scaled sources used in irradiation unit is undertaken in a safe manner.

(8) records are maintained in proper form.

(9) for inspection and maintenance procedures, approved by the competent authority.

(10) in the event of an accident persons to be notified in accordance with the procedure specified by the competent authority.

(11) the radiation zone monitor is so integrated with the personnel access door interlocks to prevent room access of specified values or if the detector malfunctions or is turned off.

(12) the monitor shall also generate audible and visible alarm signals if the radiation level exceeds that when source is in the fully shielded position.

21. Emergency procedures :-

(1) The licensee shall prepare detailed emergency procedures for each type of emergency that may reasonably be anticipated.

(2) The procedure should be brief and should be expressed in the form of instructions which can be understood by non-technical persons.

(3) The procedures should describe situations requiring emergency action and specify immediate action to be taken to minimise radiation dose to persons in the vicinity of the irradiation facility.

22. Security of irradiation facility :-

T h e licensee shall ensure that during the operation of the irradiation facility, direct surveillance of the facility is maintained in order to prevent unauthorised entry licensee shall conspicuously display the radiation into the facility.

23. Posting of radiation warning signs :-

The warning sign as given below at the site in which irradiation is in progress.

24. Radiation survey instruments :-

The licensee shall not commence operation of any irradiation facility under is control unless the irradiation facility is equipped with instruments as specified by the competent authority in Sch. VI.

25. Decommissioning :-

(1) No licensee shall decommission any irradiation facility under his control unless he :

(a) obtains the previous permission of the licensing authority ;

(b) undertakes to decommission the irradiation facility in the manner specified by the competent authority ;

(c) undertakes to bear all the expenses of such decommissioning.

(2) The licensee shall not use the site used for the irradiation facility for any other purpose, unless he obtains the certificate of release from the licensing authority.

(3) The licensing authority may on the application of the licensee and after obtaining a report from the competent authority, in its discretion issue a certificate of release.

26. Disposal of decayed sources :-

The licensee shall at his expense, ensure the safe disposal of the radioactive sources in such manner as may be approved by the competent authority.

SCHEDULE 1

Technological conditions for irradiation

			Dose(KGy)			
SI.	Name of food	Purpose of irradiation	Minimum	Maximum	Overall	Specific conditions
No.					average	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Onions	To inhibit sprouting	0.03	0.09	0.06	
			(30. Gy)	(90 Gy)	(60 Gy)	
2.	Potatoes	To inhibit sprouting	0.06	0.15	0.10	
			(60 Gy)	(150 Gy)	(100 Gy)	
3.	Forezen seafoods	To reduce the number of certain	4	6	5	Irradiation should
		pathogenic microorganisms				be carried out in a

		such				
		as Salmonella in packaged frozen				forzen state
		sea-foods.				
4.	Spices	To control insect infestation	6	14	10	Irradiation under
		to reduce microbial load and				prepacked condition
		pathorganic microorganisms				

SCHEDULE 2
Qualifications of Personnel

1. Radiological Safety Officer :-
The minimum qualification ; He should be a Science graduate with physics as one of the subjects. He should have also successfully undergone instructions specified for the training of Radiological Safety Officer. He should have also successfully undergone instructions specified for the training of Radiological Safety Officer level III as prescribed by the Atomic Energy Regulatory Board and should posses a valid certificate to that effect. The subject for instructions include fundamentals of radiation and radiation protection, concept of dose limit, use of instruments and survey techniques in radiation detection; and knowledge of personnel monitoring equipments, inspection and maintenance of safety interlocks, and operation and emergency procedures.

2. Operator :-
The operator should be Science graduate Diploma holder either in Electrical or Mechanical Engineering. The subject for inclusion in the instruction of the operator will be the same as those prescribed for Radiological Safety Officer except that he shall be given training in elements of food technology and food irradiation technology also. Food Irradiation Technology :

(a) Details of radiation sources used for food irradiation.

(b) Measurement of absorbed doses during irradiation using proper dosimeter for various types of sources and maintenance of the record of dosimetry and source activity.

(c) Source-product geometry to increase efficiency of radiation utilization.

(d) Operation of radiomclide irradiator to ensure correct

operational and of correct safe position of the source which should be interlocked with the product movement.

(e) Maintenance of irradiator.

(f) Irradiation technology of individual food items.

3. Quality Control Officer :-
The qualification of the Quality Control Officer should be either M.Sc./B. Tech. in Microbiology, Food Technology or Food Chemistry.

(1) The Quality Control Officer shall ascertain the quality of the food.

SCHEDULE 3
Document to be submitted to the competent authority for obtaining approval of irradiation facilities.

1. . :-
The complete design drawings of the facility indicating the details of the shielding, surrounding the source, wall thickness, labyrinth access, openings voids, reinforcements, mechanical and electrical safety system, ventilation, fire protection systems.)

2. . :-
The environs of the facility including residential complexes, occupancy within 50 m radius of the facility, geology of the location, water table, soil characteristics, stismicity.

3. . :-
Complete description of the radiation source, address of the supplier and the operating condition of the source such as source drive system.

4. . :-
Safety analysis report to demonstrate the adequacy of radiation safety under normal and anticipated accident conditions.

SCHEDULE 4(i)
A. Condition for the operation of irradiation facilities.

1. Introduction :-

1.1 Only irradiation facilities based on the use of either a radionuclide source (60C° or 137Cs) or X-rays and electrons generated from machine sources should be used.

1.2 The Irradiation facility, may be of two designs either

"continuous" or "batch" type.

1.3 The irradiation facility shall make use of accepted methods for measuring the absorbed radiation dose and of the monitoring of the physical parameters of the process.

2. Irradiation plants :-

2.1 The manufacturer of the facility should state the activity of the source in Becqueal (Bq) in the case of radionuclide source, and it should be recorded, The recorded activity should take into account the natural decay rate of the source and should be accompanied by a record of the date of measurement or recalculation.

2.2 The irradiation facility using radionuclide sources shall have a well separated and shielded depository for the source element and a treatment area which can be entered only when the source is in the safe position.

2.3 There should be a positive indication of the correct operational and of the correct safe position of the same which should be interlocked with the product movement system.

2.4 In the case of machine sources the average beam power should be adequately recorded.

2.5 There should be a positive indication of the correct setting of all machine parameters which should be interlocked with the product movement system.

2.6 A beam scanner or a scattering device (e.g., the converting target) must be incorporated in a machine source to obtain an even distribution of the radiation over the surface of the product.

2.7 The product movement, with width and speed of the scan and the beam pluse frequency (if applicable) should be adjusted to ensure a uniform surface dose.

3. Dosimetry and Process Control :-

(1) Certain dosimetry measurements (para. B) should be made prior to the irradiation any food stuff.

(2) The dosimetry measurement should be done for each new food irradiated, irradiation process, and whenever modifications are made to source strength or type and to the source product

geometry.

(3) Routine dosimetry should be made during operation and records of such measurements must be available for inspection.

(4) The measurements of facility parameters governing the process such as transportation speed, dwell time, source exposure time, machine beam parameters, should be made regularly during the operation and record must be kept for inspection.

4. Good radiation processing practice :-

(1) The design of the irradiator should have the facility to optimize the dose uniformity ratio to ensure appropriate dose rates and where necessary to permit temperature control during irradiation (e.g., for treatment of frozen food) and also control of atmosphere.

(2) Care must be exercised to minimize mechanical damage to the product during transport, irradiation and storage and to use irraditor to its maximum efficiency.

(3) Where the food to be irradiated is subjected to special standards for hygiene or temperature, control, the facility must permit compliance with these standards.

5. Product and Inventory Control :-

(1) The incoming product should be physically separated from the outgoing irradiated product.

(2) Where appropriate, a visual colour change radiation indicator should be affixed to each product pack for ready indentification of irradiated and non-irradiated products.

(3) Records should be kept in the facility record book which show the nature and kind of the product being treated, its identifying marks if packed or , if not, the shipping details, its bulk density the type or source or electrol machine, the dosimetry, the dosimeters used and details, of their calibration, and the dates of the treatment.

(4) All products shall be handled, before and after irradiation, according to accepted good manufacturing practices taking into account of the particular requirements of the technology or the process (Schedule I). Suitable facilities for refrigerated storage may be required.

SCHEDULE 4(ii)
B. Dosimetry

1. The overall average absorbed dose :-

It can be asumed for the purpose of the determination of the wholesomeness of food treated with an overall average dose of 10 kGy or less, that all radiation chemical effects in that particular dose range are proportional to dose. The overall average dose, D, is defined by the following integral over the total volume of the goods. D = J (x, y, z), d(x, y, z).dv M where M = the total mass of the treated sample l = the local density at the point (x, y, z) d = the local absorbed dose at the point (x, y, z) dv = dx dy dz the infinitesimal volume element which in real case is represented by the volume fractions. The overall average absorbed dose can be determined directly by homogeneous products or for bulk goods of homogeneous bulk density by distributing an adequate number of dose meters strategically and at random throughout the volume of the goods. From the dose distribution determined in this manner an average can be calculated which is the overall average absorbed dose. If the shape of the dose distribution curve through the product is well determined the positions of minimum and maximum dose are known. Measurements of the distribution of dose in these two positions in a series of samples of the product can be used to give an estimate of the overall average dose. In some cases the mean value of the average values of the minimum (Dmin) and maximum (Dmax) dose will be a good estimate of the overall average dose, i.e., in these cases. Dmax + Dmin over average dose =

2. Effective and limiting dose values :-

(1) Some effective treatment e.g., the elimination of harmful microorganisms or a particular shelflife extension or a disinfestation requires a minimum absorbed dose. For other applications too high an absorbed dose may cause undesirable effects or an impairment of the quality of the product.

(2) The design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process. In some low dose applications it will be possible within the terms of paragraph 4 on Good Radiation Processing Practice to allow a ratio of maximum to minimum dose of greater than 3.

(3) With regards to the maximum dose value under acceptable wholesomeness considerations and because of the statistical distribution of the dose of mass fraction of product of a least 97.5% should receive and absorbed dose of less than 15 kGy when the overall average dose is 10 kGy.

3. Routine dosimetry :-

Measurements of the dose in a reference position can be made occasionally throughout the process. The association between the dose in the reference position and the overall average dose must be known. These measurements should be used to ensure the correct operation of the process. A recognized and calibrated system of dosimetry should be used. A complete record of all dosimetry measurements including calibration must be kept.

4. Process Control :-

(1) In the case of a continuous irradiation facility employing radionuclide, it will be possible to make automatically a record of transportation speed or dwell time together with indications of source and product positioning. These measurements can be used to provide a continuous control of the process in support of routine dosimetry measurements.

(2) In a batch operated radionuclide facility automatic recording of source exposure time can be made and a record of product movement and placement can be kept to provide a control of the process in support of routine dosimetry measurements.

(3) In a machine facility a continuous record of beam parameters, e.g., voltage, current, scan speed scan width, pulse repetition and a record of transportation speed through the beam can be used to provide a continuous control of the process in support of routine dosimetry measurement.

SCHEDULE 5

General conditions for Irradiated Foods

1. Scope :-

These conditions applies to food processed by irradiation. It does not apply to foods exposed to doses imparted by measuring instruments used for inspection purposes.

2. General Conditions for the Process :-

(1) Radiation Source. The following types of ionizing radiation may

be used :

(a) Gamma rays from the radionuclides 60Co or 137 Cs :

(b) X-rays generated from machine sources operated at or below an energy level of 5 MeV ;

(c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

(2) Absorbed Dose. The overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy.

(3) Facility and Control of the Process.

2.3.1. Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by the licensing authority.

2.3.2. The facilities shall be designed to meet the requirements of safety, efficacy and good hygienic practices of food processing.

2.3.3. The facilities shall be staffed by adequately trained and competent personnel.

2.3.4. Control of the process within the facility shall include the keeping of adequate records including quantitive dosimetry.

2.3.5. Premises and records shall be open to inspection by appropriate national authorities.

3. Technological Requirements :-

(1) Conditions for Irradiation. The irradiation of food is justified only when it fulfills a technological need.

(2) Food Quality and Packaging Requirements. The doses applied shall be commensurate with technological and public health purposes to be achieved and shall be in accordance with good radiation processing practice. Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this purpose and shall be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the technology of the process.

4. Labelling :-

(1) Inventory control. For irradiated foods, whether prepacked or not, the relevant shipping documents shall give appropriate

information to identify the registered facility which has irradiated the food, the date(s) of treatment and lot identification.

(2) Prepacked foods intended for direct consumption. The labelling of prepackaged irradiated foods shall be in accordance with the relevant provision given in Prevention of Food Adulteration Rules.

(3) Food in bulk containers. The declaration of the fact of irradition shall be made clear on the relevant shipping documents.

5. Re-Irradiation :-

(1) Except for foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect reinfestation, foods irradiated in accordance with 2 and 3 of this standard shall not be re-irradiated.

(2) For the purpose of this standard food is not considered as having re-irradiated when

(a) the food prepared from materials which have been irradiated at low levels e.g., about I kGy, is irradiated for another technological purpose.

(b) the food containing less than 5% of irradiated ingredient, is irradiated, or when

(c) the full dose of ionizing radiation required to achieve the desired effect is applied to the food is more than one instalment as part of processing for a specific technological purpose.

(3) The cumulative overall average dose absorbed should not exceed 10 kGy as a result of re-irradiation.

SCHEDULE 6
SCHEDULE 6

(See Rule 24) Radiation Survey Instruments required for radiation monitoring. Either A. 1. Radiation Survey Meter (G.M. Type 0.2.mR/hr. or with other appropriate measurement range). and 2. Radiations Survey Meter (Ionization chamber type 0-5R/hr. or with other appropriate measurement range). or B. 1. Wide range Survey Meter (G.M. Type 0-100R/hr. or with other appropriate measurement range). 2. Alternatively, any single or combination of radiation survey meters recognised by the competent authority as equivalent to the above.

SCHEDULE 7
SCHEDULE 6

SCHEDULE 8
Operational Limits

1. . :-
The cumulative effective dose constraint for five years from 1st January 1994 to 31st December 1998 will be one hundred milli Sievert (100 mSv). for individual radiation workers.

2. . :-
The annual effective dose to individual workers in any calendar year during the five-year block shall not exceed the limit of thirty milli Sievert (30 mSv).

SCHEDULE 9
Leakage and safety related tests

1. Wet storage irradiators :-

(1) The resin bed in the water conditioning system shall be daily checked with a radiation survey instrument. The survey instrument should be sensitive enough to detect minimum radioactivity of 2000 Eq. in the resin bed. In the event of detection of activity above this level, water circulation system shall be stopped and irradiator shall be withdrawn from service.

(2) In addition the pool water shall be checked for contamination by using an on-line radiation monitor on a pool water circulating system.

(3) The detection of above normal radiation levels must activate an alarm. Activation of alarm must automatically cause the water purification system to shut off.

2. Dry storage irraditors :-
Swipe test using a moist paper of 100 square centimeter area shall be conducted weekly on the closest accessible surface near the source in storage condition. Activity on the sample shall be counted by a radiation survey instrument with a minimum detection capability of 2000 Bq on swipe sample. In the event of detection of activity above this level, irradiator shall be withdrawn from service.