

JUN 09 1992

Kidde-Fenwal, Inc.
ATTN: Robert A. MacNutt
Quality Manager
400 Main Street
Ashland, Massachusetts 01721

Dear Mr. MacNutt:

Enclosed is Amendment No. 01 to NRC License No. 20-15285-03E, changing the name of your company, adding a new model smoke detector, and listing the smoke detector models by series.

You stated in your letter dated May 27, 1992, that Nohmi Bosai, Ltd. receives the source in the form of a foil, which they then assemble into a holder. In your letter dated April 1, 1992, you stated that Nohmi Bosai, Ltd. will perform wipe testing using a lot tolerance percent defective of 5.0 percent, which will be acceptable at this time. However, please note that the Sealed Source and Safety Section's current standards for quality control procedures requires a 100% testing for contamination by the manufacturer or yourself if the sources are received as foils and subsequently assembled into holders. I have enclosed a copy of the QC Program Requirements for the Manufacture and Distribution of Smoke Detectors from the Sealed Source and Safety Section for your use in submitting your license renewal application. We will evaluate your quality control procedures against this standard during our review of your license renewal application.

Please review the enclosed document carefully and be sure that you understand all the conditions. If there are any errors or questions, please contact me so that appropriate corrections and answers can be provided.

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the U.S. Nuclear Regulatory Commission, now or hereafter in effect, to include the following:

1. Operate in accordance with NRC regulations in 10 CFR Part 19, "Notices, Instructions, and Reports to Workers: Inspection and Investigations;" 10 CFR Part 20, "Standards for Protections Against Radiation;" and other applicable regulations.
2. Use radioactive material only for the purpose(s) indicated in your license.
3. Notify NRC in writing of any change in mailing address (no fee is required if the location of radioactive material remains the same).

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Kidde-Fenwal, Inc.

- 4. Request and obtain appropriate amendments if you plan to change control or ownership of your organization, change locations of distribution of radioactive material, or make any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with NRC. A license fee may be charged for the amendments if you are not in a fee-exempt category.
- 5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
- 6. Request termination of your license if you plan to permanently discontinue activities involving radioactive material, see 10 CFR 30.36.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions, please contact me at (301) 504-2611.

Sincerely,

DISTRIBUTION:

License File
 TTaylor
 IMAB r/f
 IMNS Central File
 NMSS r/f
 JGlenn
 MLamastra
 Region I
 OSP

Original signed by:

Torre Taylor
 Commercial Section
 Medical, Academic, and Commercial
 Use Safety Branch
 Division of Industrial and
 Medical Nuclear Safety, NMSS

Enclosures:

- 1. Amendment No. 01
- 2. QC Program Requirements for the Manufacture and Distribution of Smoke Detectors

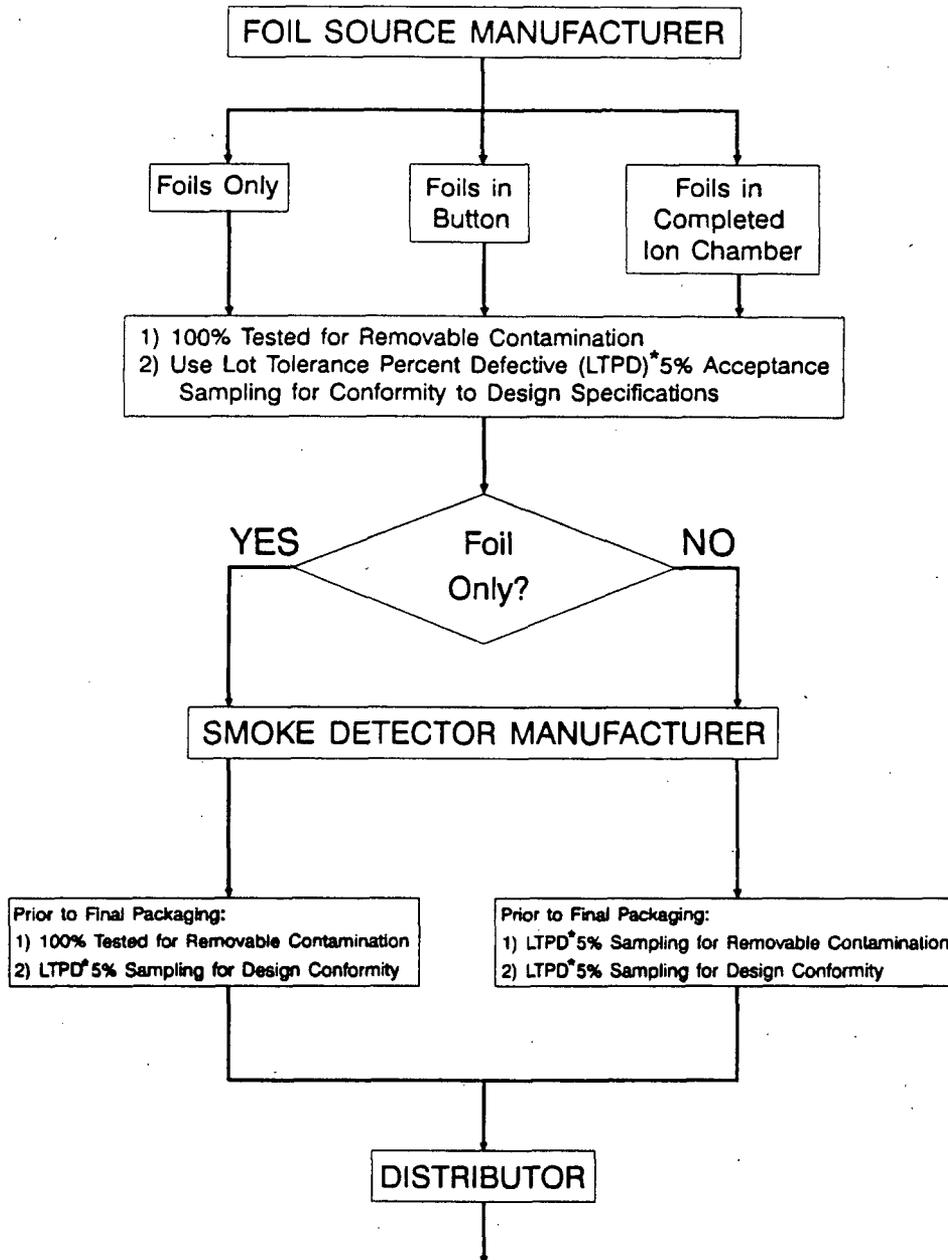
OFC	:IMAB:NMSS	:IMAB:NMSS	:	:	:	:	:
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QC Program Requirements for the Manufacture and Distribution of Smoke Detectors

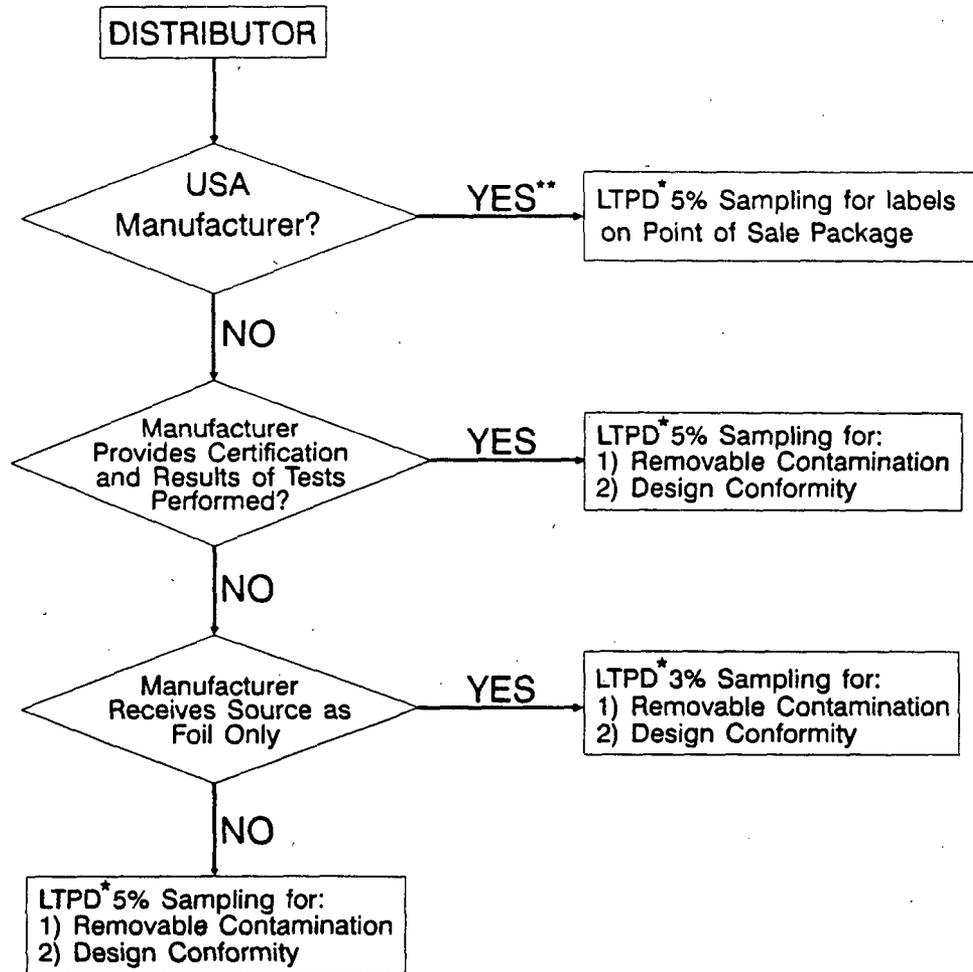
10 CFR Part 32.29 requires an applicant to provide information on an adequate Quality Control program to ensure that each production lot meets the design standards approved by the Nuclear Regulatory Commission

The following flowchart and text represent the requirements which have been deemed appropriate for such a program. Applicants are encouraged to use this approach or submit, in detail, an equivalent alternate program.

QC Program Requirements for the Manufacture and Distribution of Smoke Detectors (Cont'd)



QC Program Requirements for the Manufacture and Distribution of Smoke Detectors (Cont'd)



* Note: LTPD Acceptance Sampling is based on the attached charts.

** Note: Based on reliability/inspectability of USA Fabrication Records and Facilities

Definitions:

1. **Acceptance Number (c)** means the largest number of defectives (or defects) in the sample or samples under consideration that will permit the acceptance of the inspection lot.
2. **Acceptance Sampling** means sampling inspection in which decisions are made to accept or reject product; also, the science that deals with procedures by which decisions to accept or reject are based on the results of the inspection of samples.
3. **Defect** means an instance of a failure to meet a requirement imposed on a unit with respect to a single quality characteristic.
4. **A Defective** means a defective unit; a unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.
5. **Design Conformance** means a complete unit which has been inspected and has been shown to meet the design specifications which were submitted to, and approved by the NRC. Design specifications include detailed information about labeling, point of sale packaging, and detector construction.
6. **Disposition of Lot:** If any units within a sample are observed to be defective then the entire lot must either be rejected or inspected. All failed units must pass the test criterion prior to release.
7. **Final Packaging** is the packaging in which the unit is contained for sale to the end user. Also known as market package.
8. **Inspection** means the process of measuring, examining, testing, gauging, or otherwise comparing the unit with the applicable requirements.
9. **Lot Tolerance Percent Defective (LTPD)** is defined by the American Society for Quality Control as "... expressed in percentage defective, the poorest quality in an individual lot that should be accepted."
10. **Quality Characteristics** are the test criteria. The devices must have less than 0.005 microcurie of removable contamination and conform to the manufacturer's design specifications (ex. Labeling, packaging, construction, etc.). Up to 75 units may be tested for removable contamination using one swipe. The trigger level for multiple units using one swipe is 0.005 microcurie.
11. **Sample (n)** means, in acceptance sampling, one or more units of product (where n is the number of units) drawn from a lot for purposes of inspection to reach a decision regarding acceptance of the lot.
12. **Sampling at Random** as commonly used in acceptance sampling theory, means the process of selecting sample units in such a manner that all units under consideration have the same probability of being selected.

For our purposes, the LTPD tables found in 10 CFR Part 32.110 and Regulatory Guide 6.6 have been modified whereby the acceptance number for all lot sizes is zero (0). The reasoning behind this change is that from a health and safety standpoint no defects in these devices are acceptable. If defective units are found within the sample, the entire lot shall either be rejected or inspected for conformance to the quality characteristic(s) which the sample units were found to be defective. All units which are found to be defective must conform to the quality characteristic(s) prior to release or be rejected entirely. It is recommended that the choice of samples be as random as possible in order to provide the maximum probability that a defect will be detected.

The following are the modified 3% LTPD and 5% LTPD tables:

LTPD = 3%

LOT SIZE	<i>n</i>	<i>c</i>
1 - 40	All	0
41 - 55	40	0
56 - 100	55	0
101 - 200	65	0
201 - 500	70	0
501 - 3000	75	0
3001 - 100,000	130	0

LTPD = 5%

LOT SIZE	<i>n</i>	<i>c</i>
1 - 30	All	0
31 - 50	30	0
51 - 100	37	0
101 - 200	40	0
201 - 300	43	0
301 - 400	44	0
401 - 2000	45	0
2001 - 100,000	75	0

Rational for Certain Requirements:

Foil source suppliers can be divided into three general categories; 1) Manufacturers who supply only foil sources, 2) Manufacturers who supply foil sources installed in button holders, 3) Manufacturers who supply foil sources installed in complete ion chambers. All source manufacturers are required to ensure each source is tested, and meets the requirements for removable contamination prior to delivery to the smoke detector manufacturer. Foils installed in buttons and/or completed ion chambers tend to be better protected from abrasion or mishandling. Accordingly, these sources have a lesser chance than unprotected foil sources of being damaged during installation into a smoke detector. Therefore, smoke detector manufacturers who receive foil sources only, must additionally test each smoke detector or ion chamber assembled for removable contamination prior to the final packaging of the device. Conversely, smoke detectors which are manufactured using a foil source received in a button or a completed ion chamber need only be tested for removable contamination according to the LTPD 5% table. All smoke detectors, regardless of manufacturer, must be tested for conformance to design specifications according to the LTPD 5% table. This yields a 95% confidence level that the devices meet design specifications.

Prior to a smoke detector being distributed in the U.S. the foil source, button or ion chamber used in the device must be registered with the NRC according to Regulatory Guide 10.10 or 10.11. Smoke detector manufacturers can be located inside or outside the U.S. The NRC cannot always have access to the records of foreign manufacturers since inspection of the manufacturers is not always possible. The records and facilities of manufacturers and distributors located within the U.S. are always available for inspection by the NRC. Therefore distributors who receive complete devices from a U.S. manufacturer need not conduct further testing for removable contamination and/or design conformity. This testing is conducted by the manufacturer and can easily be verified. Accordingly, distributors who receive devices from U.S. manufacturers need only check the devices for the appropriate labeling on the point of sale packaging according to the LTPD 5% table.

Since foreign manufacturers cannot easily be inspected, tests for removable contamination and design conformity performed by these manufacturers cannot easily be verified. The distributor must provide assurance that devices received from a foreign manufacturer have been tested for these criteria. This is accomplished by the distributor conducting lot sampling of the devices. If the foreign manufacturer provides a written certification that these tests were performed as well as the results of these tests, then the distributor need only perform lot sampling for these criteria according to the LTPD 5% table. However, if the foreign manufacturer does not provide a certification and the test results, and if the manufacturer received the source in foil form only, then the distributor must perform lot sampling for these criteria according to the LTPD 3% table. This yields a 97% confidence level that the devices are within removable contamination limits and meet design specifications. The reason the additional level of confidence is needed goes back to the fact of unprotected foil sources being more susceptible to damage during shipment and installation. If, however, the foreign manufacturer receives the source in a button or a completed ion chamber from a U.S. manufacturer then the distributor need only test the devices for removable contamination and design conformance according to the LTPD 5% table, even if the manufacturer does not provide a certification and test results.