



GUIDE 27

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**Guidelines for corrective action to be
taken by a certification body in the
event of misuse of its mark of
conformity**

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Foreword

This document was drawn up by the ISO Committee on certification, ISO/CERTICO.
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Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity

1 Introduction

1.1 The purpose of this paper is to identify a series of procedures which a national certification body (non-governmental) should consider in deciding how to respond to :

- a) a reported misuse¹⁾ of its registered mark of conformity, or
- b) a situation in which a certified product is subsequently found to be hazardous²⁾.

The action that a certification body chooses will depend upon a number of factors such as : the laws of the country in which the misuse occurs; the nature of the contract or agreement between the certification body and the party misusing the mark; the seriousness of the misuse; whether the misuse was inadvertent or deliberate; whether the product is hazardous³⁾.

It is recognized that a manufacturer or distributor of a product can be involved in two distinctly different ways, namely, as a misuser or as a producer or distributor of a marked product which subsequently is found to be a hazardous product.

It is also recognized that the ability to foresee all potential forms of misuse or other forms of use that might develop and which might result in a marked product becoming hazardous is exceedingly more difficult than to safeguard the obvious and common forms of misuse. While the hazards arising from these different situations both require corrective actions the assessment of responsibility in each situation requires quite different considerations.

In deciding upon what action is might take, the certification body will be motivated by a desire to protect the integrity of its mark, to assist persons who may be misled by the misuse of the mark and to provide equity to competitive users of the mark, while being cognizant of the problem of mass production and distribution. The corrective action described herein is based on the premise that, in general, the following conditions exist :

1.1.1 The certification system involves the use of a mark of conformity which is applied to each certified product.

1.1.2 The certification body has its mark of conformity registered or in other ways the use of its mark protected under at least the law of the country in which it is headquartered.

1) Misuse may take a variety of forms such as :

- a) misapplication of mark or non-conforming products, e.g. a non-conforming product may result from a violation of a contract, inadequate quality control, or error in assessment of conformity by a certification body or laboratory;
- b) unauthorized use of the mark, e.g. mark appearing on non-certified products.

2) Some reasons for which product may be found to be subsequently hazardous are :

- a) inadequate standards;
- b) unanticipated end-use of a product;
- c) a manufacturing defect.

3) This document is limited to corrective action applying to a mark of conformity; the case of certificates of conformity might be considered at a later stage if a demand exists. The document is directed at non-governmental certification bodies, although it could also be used by governmental certification bodies operating similar types of certification systems.

1.1.3 A contractual arrangement or legal agreement concerning the use or misuse of the mark of conformity exists between the certification body and the party authorized to use the mark.

1.1.4 The party authorized to use the mark is capable of exercising continuous control over the certified product(s) to ensure that all terms of the contract are met.

1.1.5 The mark of conformity cannot be applied to a product except upon authorization and control of the certification body which owns the mark.

1.2 Certification bodies will normally take strong corrective action when their mark is counterfeited and applied without any form of contract or agreement. The action that can be taken depends in part upon the laws of the country in which the counterfeiting and misuse occurred.

2 Definitions

2.1 recall : The action by which the misuser or the producer of a subsequently hazardous product or other party responsible for making the product available withdraws the products from users, the marketplace or distribution sites and returns them to the factory or other acceptable location for corrective action.

NOTE — Because of legal problems of ownership, recall must be effected by the manufacturer or other party responsible for products' distribution.

2.2 misuser : Any person, organization or other corporate body that has misused the mark of conformity whether or not the product is eligible to bear the mark.

2.3 producer of a subsequently hazardous product (POSHP) : Any person, organization or other corporate body that has been complying with all requirements of the certification body, has properly applied the mark of conformity of that body to the product(s) involved but has learned that the product(s) has (have) been found to be "hazardous".

2.4 hazardous : With respect to a manufactured product, means exposing life, limb or property to dangerous or imminently dangerous conditions. A hazardous product is considered to exist if the quantity of products involved is such as to constitute an unacceptable percentage, and there is either

- a) an unsafe construction, or
- b) the product is gaining widespread use in applications not foreseen when the standard was written, such applications in turn being ones for which the product was not certified, and
 - no specific scope of applications has been provided in the standard, and
 - no limiting scope of applications has been provided by the manufacturer in written material accompanying the product at point of sale.

NOTE — Where an inherent hazard is necessary for the product to perform its intended function, e.g. rotating beaters of a food mixer, such a hazard shall not be considered "hazardous" as used in the context of this definition.

2.5 corrective action : This is an action requested of the misuser or of a POSHP or other party responsible for making the product available as considered appropriate by the certification body to eliminate the consequences of the misuse and to remove the hazard as far as necessary and practically possible.

3 Conditions under which corrective action is taken

3.1 The certifying body requires a misuser to take corrective action whenever the mark of conformity has been affixed to a product that

- is hazardous, or
- is not authorized to bear the mark of conformity, e.g. because there is no record of the product in question having been certified; or does not comply with the applicable certification requirements to the extent that the integrity of the mark of conformity is jeopardized, or

- bears an unauthorized form of mark of conformity (e.g. counterfeit certification label), or
- is in violation of the certification agreement.

3.2 When either a report of misuse of a mark of conformity or of a hazard involved with a product bearing a mark of conformity is received by the certifying body, the validity of the report should be investigated. Where it is established that misuse has occurred, the certifying body should determine the scope of misuse, including products, model number, serial numbers, factory production facilities, production runs and quantities involved.

4 Types of corrective action

Corrective action could be one or more of the following :

- a) notification by the certification body of parties authorized and responsible for instituting a recall when, in the opinion of the body, such recall is necessary to protect the public, and to permit implementation of action;
- b) removing the mark of conformity from the product. (This is normally done only at the factory or other central location so that the product in question is removed from the stockroom, marketplace, distribution sites or user's possession. Alternatively, the mark of conformity could be removed from the product on the site, provided such removal is in collaboration with the involved regulatory authorities who would then proceed to accept or reject the product.);
- c) rebuilding the product so that it complies with the governing certification requirements. (It is preferred that the rebuilding be done at the factory; however, when it is not practicable to recall some of the units in question to the factory, e.g. electric switchgear or large furnaces, rebuilding may be authorized to be done in the field.);
- d) scrapping or suitably replacing a returned product because it is not practicable either to remove the mark of conformity or to rebuild the product so that it complies with the governing certification requirements;
- e) where a hazardous condition exists and it is not practical to implement a), b), c) or d), a notice to the general public about the hazard should be issued or action taken consistent with other national legislation.

NOTE — Where a "POSHP" is involved the certification body should itself take corrective action to take the initiative to have the standard requirements upgraded to eliminate the hazard and to take such action as to ensure that products involving the same hazard do not bear the mark of conformity.

5 Choice of action against the misuser

5.1 The type of corrective action to be taken will be influenced by the nature of the misuse and its subsequent consequences.

5.2 When the mark of conformity has been used but not under contract or not in compliance with the contract, legal proceedings might result in a court of law deciding what the corrective action will be.

6 Timing of corrective action

6.1 When the facts indicating a need for corrective action are conclusive, the certification body will initiate corrective action immediately provided there is a misuser to be held responsible for such action or a POSHP.

6.2 When the facts are conclusive and corrective action is indicated but there is no misuser or POSHP to be held responsible (e.g. the company is bankrupt), or the product in question has not been produced for a number of years and is no longer available in the marketplace, the certification body should obtain advice from legal counsel and notify appropriate governmental, regulatory and public bodies.

7 Initiating corrective action with misuser

7.1 When there is conclusive proof that a product is hazardous or is involved in misuse of the mark of conformity, corrective action should be initiated by the body that certified the product. In such instances, the misuser of the mark and, where appropriate, the regulatory authorities shall be notified immediately by telephone or telex of the problem, and authorization to apply the mark of conformity to the involved product shall be suspended.

7.2 Also in the case of a hazardous product bearing the mark of conformity, the certification body should inform the misuser of the need to take appropriate user notification action, advising of the hazard and the action to be taken.

7.3 The initial notification to the misuser should always be confirmed in writing by registered (or equivalent) letter with copies to the appropriate regulatory authorities and/or other bodies when relevant. (This letter is written to suit the particular circumstances, e.g. depending on whether or not it is practicable for the product in question to be recalled to the factory.) In either case it would normally contain : the reason(s) for corrective action, any hazardous conditions that may exist, the actions to be taken by the misuser to resolve the problem and a statement covering the action to be taken to ensure that the mark of conformity is not applied to ineligible products.

8 Completing a successful corrective action with a misuser who has an agreement with the certification body

When the corrective action has been resolved to the satisfaction of the certification body, the following should be undertaken :

- a) All recipients of the letter which called for corrective action should be sent a second letter which.
 - states the suspension imposed upon the misuser has been lifted and that authorization to use the mark of conformity has been reinstated;
 - summarizes the corrective action taken by the misuser;
 - when applicable, describes the new marking required to distinguish the product in its corrected state from its previous unacceptable condition.
- b) Certification records should be revised to include any modifications necessitated by the corrective action.

The certifying body shall also carry out an audit of :

- its own approval and surveillance duties to determine whether part of the misuse is due to a weakness in its own organization;
- its procedures to determine the means whereby the approval and surveillance responsibilities of the certifying body, or its laboratory, can be altered to ensure so far as realistic to do so that such a misuse of the mark cannot be repeated.

9 Degree of corrective action to be achieved

9.1 The certification body desires the corrective action to be taken on one hundred percent of the particular product involved. This, of course, frequently is not possible, especially if the product has been on the market for a considerable time. Normally the certification body considers that corrective action as appropriate has been carried out satisfactorily if :

- a) the misuser has made a proper public announcement when asked to do so;
- b) the products in the marketplace and distribution sites have been recalled, rebuilt, replaced or destroyed under supervision, or other corrections thereto made as required to the maximum degree feasible;
- c) the misuser has agreed to continue the required corrective action on units which are in the possession of the user until the certification body is satisfied that the maximum practical result has been achieved, and
- d) such necessary steps have been instituted in the manufacturing process to obviate the production of products which will again require similar corrective action.

10 Refusal to take corrective action

10.1 When a misuser refuses to take corrective action, the following steps should be taken by the certification body :

- a) cancellation of appropriate certification contracts with the misuser may be processed;
- b) regulatory authorities involved and/or other bodies, when relevant, shall be informed that the misuser has refused to take corrective action and that certification contracts in the name of the misuser have been cancelled, where the severity of the case warranted such action;

c) legal counsel shall be obtained as to other action that may be taken (e.g. court injunctions, a press release by the certification body prosecution).

10.2 A POSHP would probably take corrective action voluntarily upon learning that his product contained a hazard even though conforming to the applicable standard(s).

10.3 In the unlikely event that the POSHP refused to take corrective action, discussions with concerned regulatory authorities and legal counsel should be held to decide upon a course of action. In addition to action that regulatory authorities might take, some possible courses of action open to the certification body would include

- a) obtaining rapid revision of the standard to eliminate the hazard and requiring all certified products of the type involved to meet the new criteria at an early date following publication of the revision to the standard, and
- b) notifying the public of the discovered hazard via the most appropriate news media.

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