

HAR AGREEMENT	PERMANENT DOCUMENT	PD - 4
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SURVEILLANCE PROCEDURES

CONDITIONS FOR REDUCED SAMPLING

Approved by the HAR Group on 26th September 1994

Ratified by the Advisory Committee on 27th September 1994

Rationale: PD-5 has been withdrawn (D77/25, Bergamo Meeting) and was replaced by Annex 1
in PD-D

Issue October 1994 (editorial rev. July 1995 and October 2024)

0. **Introduction**

This Permanent Document specifies the conditions under which the reduced sampling scheme foreseen in Article 4 of PD-C can be awarded to HAR licensees (For a better understanding of the process please see flow-chart in Annex 1 and the example given in Annex 2).

The reduced sampling scheme mentioned above is the following:

- 75 samples per calendar year, but not less than 25 per place of manufacture.
- 4 visits per year per place of manufacture.

1. **Starting conditions**

The reduced sampling can be awarded to the licensee if all the following conditions are fulfilled:

- a) a Quality System is satisfactorily implemented according to Permanent Document PD-D5, including adequate process control to ensure conformance with standards;
- b) the total of the deviation values, during the 4 visits preceding the application for the reduced sampling scheme, must be less than or equal to 40 % of the value for normal surveillance given in PD-D, Table 4, Column 2.
- c) no deviations classified as "major" shall have been recorded during the mentioned last 4 visits.

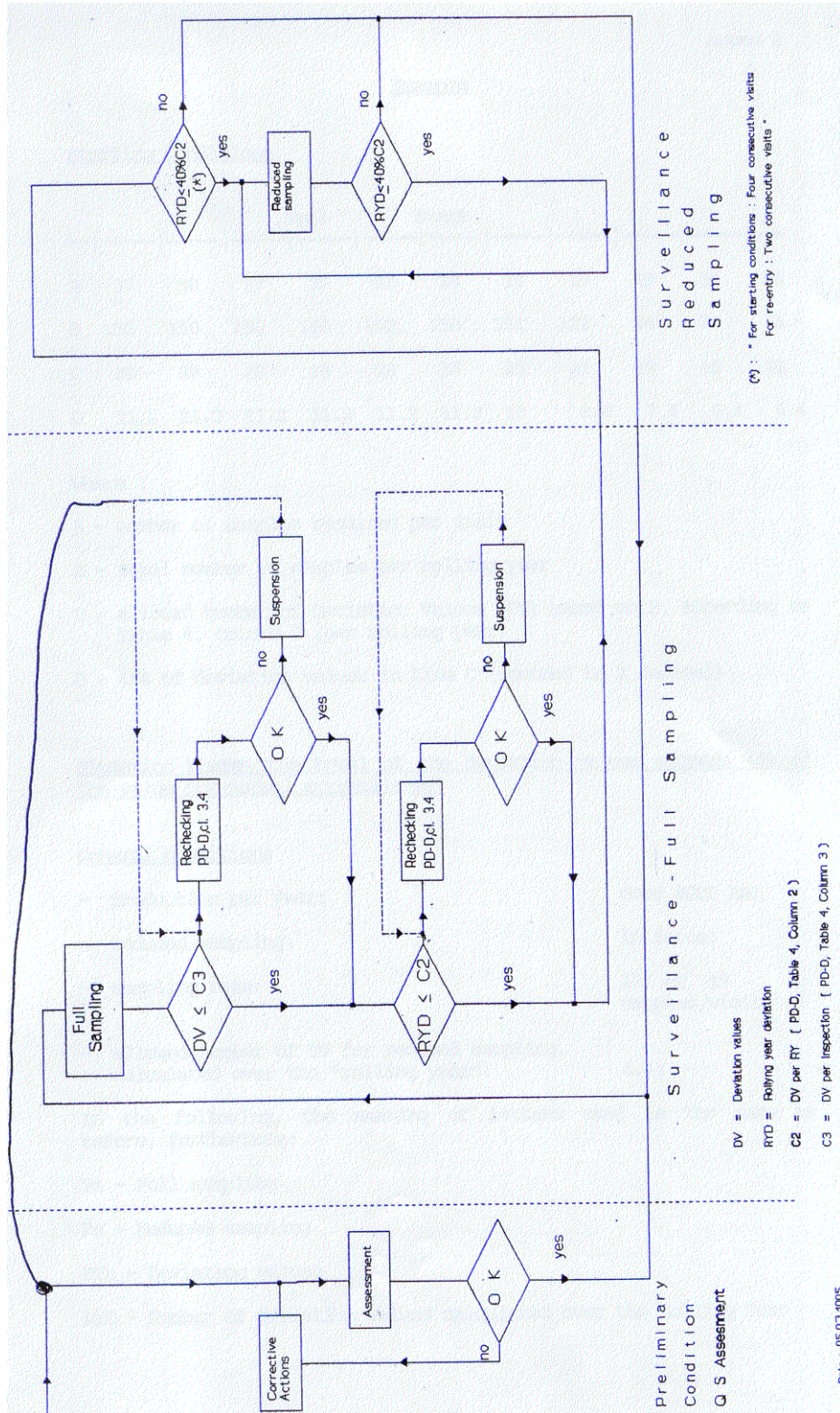
If the above requirements are met, reduced sampling will begin in the visit immediately after the date of application.

When calculating the allowed number of deviation values, the number shall be rounded to one decimal.

2. **Continued participation in reduced sampling**

Continued participation in reduced sampling is dependent on the fulfilment of conditions a) and b) in Paragraph 1.

In regard to the fulfilment of condition b), if the total of the deviation values exceeds the 40% of the value for normal surveillance (rounded to 1 decimal) given in PD-D, Table 4, Column 2, the manufacturer will be immediately returned to the normal procedure. The manufacturer will need two consecutive visits at less than or equal to 40% of the value for normal Column 2 surveillance before re-entry into the reduced sampling scheme.



24.10.94 BGG/nm

Example

Starting Conditions

	Appl					Start					
A	37	38	37	38	37	38	18	19	19	19	18
B	150	150	150	150	150	150	131	112	94	75	75
C	28	28	28	28	28	28	25	22	19	16	16
D	11.2	11.2	11.2	11.2	11.2	11.2	10	8.8	7.6	6.4	6.4

where :

A - number of samples required per visit

B - total number of samples per rolling year

C - allowed number of Deviation Values (DV) based on B, according to Table 4, Column 2 (per rolling year)

D - 40% of deviation values in Line C (rounded to 1 decimal)

Situation where "the total of the deviation values exceeds 40% of the value for normal surveillance"

General conditions

- production per year: over 8000 km;
- reduced sampling: in force;
- sampling rate: 18 or 19 samples/visit;
- allowed number of DV for reduced sampling, calculated over the "rolling year": 6.4.

In the following, the meaning of letters used is the same as before, furthermore:

Fs - Full sampling

Rs - Reduced sampling

DVs - Deviation values

RYD - Number of deviation values calculated over the Rolling Year

Situation where the manufacturer is returned to full sampling and then re-admitted to reduced sampling

Visit	1	2	3	4	5	6	7	8	9	10
Sampling	Rs	Rs	Rs	Rs	Rs	Fs	Fs	Fs	Rs	Rs
A	19	19	19	19	19	37	38	36	19	19
B	75	75	75	75	75	94	113	130	130	112
C	16	16	16	16	16	19	22	25	25	22
D	6.4	6.4	6.4	6.4	6.4	7.6	8.8	10	10	8.8
DVs found	0	0	1.5	3.5	4	0	0	0	1	2
R Y	0	0	1.5	5.0	9.0	9.0	7.5	4	1	3
R Y # D	Y	Y	Y	Y	N	N	Y	Y	Y	Y

Comment: At the visit in 5th column the number of deviation values obtained (9.0) is greater than the allowed (6.4) and therefore the manufacturer is returned to full sampling.

Then, at the 9th visit the manufacturer is re-admitted to reduced sampling, following 2 visits equal to or less than the allowed deviations.